IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

SECURITY NATIONAL BANK, as Conservator for JMK, a minor child,	No. C11-4017-MWB
Plaintiff,	Sioux City, Iowa January 9, 2014
vs.	8:24 a.m.
ABBOTT LABORATORIES,	Volume 4 of 10
Defendant.	

REDACTED TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE MARK W. BENNETT
UNITED STATES DISTRICT JUDGE, and a jury.

APPEARANCES:

For the Plaintiff:	AMANDA BRANDY VAN WYHE, ESQ. TIMOTHY S. BOTTARO, ESQ. Vriezelaar, Tigges, Edgington, Bottaro, Boden & Ross 613 Pierce Street Sioux City, IA 51102 STEPHEN C. RATHKE, ESQ. ROBERT J. KING, ESQ. Lommen, Abdo, Cole, King & Stageberg 2000 IDS Center 80 South Eighth Street Minneapolis, MN 55402
For the Defendant:	JOHN C. GRAY, ESQ. Heidman Law Firm 1128 Historic 4th Street Sioux City, IA 51102 DANIEL E. REIDY, ESQ. JUNE K. GHEZZI, ESQ. GABRIEL H. SCANNAPIECO, ESQ. KATHRYN L. DORE, ESQ. Jones Day Suite 3500 77 West Wacker Drive Chicago, IL 60601
Also present:	Louise Deitloff Daniel Morrison
Court Reporter:	Shelly Semmler, RMR, CRR 320 Sixth Street Sioux City, IA 51101 (712) 233-3846

(Proceedings reconvened outside the presence of the jury.)

THE COURT: Is there anything we need to take up? Please be seated, everybody.

MR. REIDY: Thank you, Your Honor. I do have one thing just to sort of inform the Court.

THE COURT: Okay.

MR. REIDY: We had some documents referred to yesterday that were in the confidential stack in processing of things. Mr. Rathke and I were able to work out that we didn't need to do anything extraordinary with it. There was no one in the courtroom from one of the other competitors or anything and --

THE COURT: There was a lawyer in the courtroom, and she came up and introduced herself to me on a break, and Mr. Bottaro would know about it. She told me that Mr. Bottaro was local counsel in a case for her, and I just looked at her, and I didn't really have time to talk to her. And I just said, "Is it a baby formula case?" And she said no but --

MR. BOTTARO: It's a products liability case, completely different area. She actually wanted to check out what Judge Bennett was like and how he ran the courtroom.

THE COURT: Well, good. Now the case will settle for sure.

MR. BOTTARO: Well, we didn't have defense counsel

here, so we got half the team.

MR. REIDY: So I just wanted to make sure we had our marker in place, particularly as we get into the Catherine Donnelly testimony. We'll still try and accommodate that as we can and that we'll take up the Court's offer to not have any transcript published at this time while we work out whether we'll need to try and talk to the Court about some protection if that's needed as we go along.

THE COURT: Okay. And so is the plan to close the courtroom or not close the courtroom till you give me a heads-up?

MR. REIDY: We are not currently seeking to close the courtroom, Judge.

THE COURT: Okay.

MR. REIDY: And we'll certainly give you a heads-up.

THE COURT: Okay. And then would you just be so kind as to say when you would like the record sealed and then we'll start and then Shelly will make sure it's noted so the record -- the transcript will be under seal. But then be sure -- isn't that what we were talking about, the transcript?

MR. REIDY: Yes. Could we do this, Judge?

THE COURT: Yes.

MR. REIDY: Could we -- would the Court consider just not giving the transcript out to anybody other than the parties for now and then we can go over it? We're getting a daily copy.

And we could actually mark it up in any request we have for sealing and bring it in, you know, in a day or two after. Would that work?

THE COURT: A day or two after each witness or after the trial's over?

MR. REIDY: After the witnesses.

THE COURT: Let me just confer with Shelly to see if it's going to work with her.

(A discussion was held off the record.)

THE COURT: She said that will work fine, so what's ever easiest for the parties.

MR. REIDY: So we may wait till after the trial if that works then, Judge. As long as we get any request for the transcript, before it's acted upon you get word and you would talk to us, that would be great.

THE COURT: Okay. Great.

MR. REIDY: Thank you, Judge.

THE COURT: Thank you.

Anything?

MR. KING: Judge, just a couple of scheduling issues.

THE COURT: Yes, Mr. King. Yes.

MR. KING: We have Dr. Joyce, a treating physician, scheduled to be here at 1:30 today, and so we may need to interrupt a witness, but he'll be quite a quick witness I think. And then we're going to send Dr. Farmer home and not call him.

That will speed things up. And we've made -- taken other steps to try to tighten up our presentation.

THE COURT: Okay. And I hope I mentioned this, but if I didn't, I was remiss, but I think I might have. As soon as you find out you're not going to be calling a witness, it's much more important to let the other side know than me because all I do is scratch it off the list. They have to --

MR. REIDY: They had already done that this morning, Judge.

THE COURT: Okay. Good. Good. And in the event that you do that, you'll reciprocate, of course.

MR. REIDY: (Nodded head.)

THE COURT: Okay. Ready to have the jurors brought in if . . .

Ready?

MR. RATHKE: Yes, Your Honor.

(The jury entered the courtroom.)

THE COURT: Good morning. Please be seated.

Members of the jury, I have a little surprise for you on your next break. I love to bake cookies, so I baked some cookies for you last night. It was a brand new recipe. I didn't put any nuts in it in case anybody had a nut allergy, and they're chocolate chip oatmeal, but they're super thin and crispy, and I hope you enjoy them. And then I stopped by and got a gallon of milk for you this morning that will be in the

refrigerator, so I hope you enjoy your cookies.

Mr. Reidy, are you ready to proceed?

MR. REIDY: I am, Your Honor. Thank you.

SCOTT DONNELLY, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

CONTINUED CROSS-EXAMINATION

BY MR. REIDY:

Q. Dr. Donnelly, you'll remember talking about Cook and Thurber yesterday which you indicated or agreed were the gold standard of third-party auditors; is that right?

A. Yes.

Q. And you had a chance to look over their audits in 2007, 2008 prior to testifying in this case, that is, their Abbott audits of the Casa Grande facility?

A. Yes.

Q. And do you recall that Cook and Thurber indicated that the facility at Casa Grande was built 23 years ago and was maintained both internally and externally to original conditions?

A. Yes.

Q. And do you recall that they also said they have a management team that is involved very closely in the total day-to-day operations and that management maintains an employee base that is dedicated, committed, and stable for the production of superior quality products? Do you recall that?

A. No.

Q. Okay.

MR. REIDY: 1012B.

Q. So if I can direct your attention to the second paragraph on the page 3 of Exhibit 1012B, the Cook and Thurber report, do you see that?

A. Yes.

Q. And do you now see that Cook and Thurber did, in fact, say that they had the management that is dedicated, committed, and stable for the production of superior quality products?

A. Says they have a management team that is involved very closely in total day-to-day operations. Management maintains an employee base that is dedicated, committed, and stable for the production of superior quality products.

Q. So that was in the Cook and Thurber report that you reviewed before you testified here; right?

A. Yes. You just -- you just documented it was, yes.

Q. Okay. I just want to make sure that's the same one you saw, so you had read those words previously; right?

A. I did not read it word for word. That piece is sort of a little bit of a factory fact book piece that's part of every third-party audit. So yes, I looked at it. I read it. You read it now.

Q. So are you saying that Cook and Thurber has that same sentence in every audit they do?

A. What they'll do is they have a factory fact book, basically

some description of the operation. I've done this myself with my reports. And you'll put various parts of information like this in so that you get a general sense of what the factory is like.

Q. But you're not saying that every time that they write a report they compliment the management every single time and say they're dedicated to superior products. Do they do that every single time?

A. Okay. One, I don't know if they do it every single time.

Q. Well, that probably answers it then; right? You don't know.

A. I don't know.

Q. Okay. Do you recall Cook and Thurber in that same report from April of 2008 indicating that the equipment throughout the facility was state of the art?

A. You're going to have to put it up. I did not commit that report to memory.

Q. Okay. It's up there. It's the very next paragraph after what you've already read. It's the very next sentence. Do you see it there?

A. Correct.

Q. And they indicated that the facility, the equipment was primarily computer operated and monitored for precise controls at all phases of the operation; right?

A. Yes.

Q. And they say that based on this system, documentation of all events and -- well, I should ask it this way. I apologize. And you recall that Cook and Thurber indicated that the documentation were actively recorded and maintained for future reference. Do you recall that?
A. Yes.
Q. Okay. And Cook and Thurber noted that there had been a three-day FDA audit? Do you recall that?
A. It says there right there, detailed FDA three-day review was recently completed.
Q. Okay. And that the operations for all products were indicated to have met regulatory compliance for all criteria?
A. Yes.
Q. Now, the Casa Grande facility is in Arizona; is that right?
A. Yes.
Q. And it's in a very dry climate; is that correct?
A. Yes.
Q. And having a plant in a place with low relative humidity helps keep the factory dry; correct?
A. Yes.
Q. And having a plant in a low humidity area also reduces the bacteriological problems that -- or the microbiological problems that plants have; right?
A. One would hope so. There was recently a massive peanut recall from a factory in Arizona that would have the same dry

conditions that was in their factory, and it didn't have any impact on their factory being closed to salmonella contamination.

Q. But you've said that in general the presence of a factory in a dry climate reduces the amount of microbiological contamination issues; right?

A. It can, yes.

Q. And it has in your experience; right?

A. Yes, as a general statement, yes.

Q. Well, it's more than just a general statement because when you were at Wyeth you had fewer problems with your Mexico City plant because it was in a high and dry location than you did at your plants that were in more wet and temperate locations; isn't that correct?

A. That's partially true.

Q. And you've said that before; right?

A. I've -- I've -- yes.

Q. Now, you've indicated that the manufacturing process in terms of the way the process is set up at Casa Grande was very similar to the Wyeth process; is that right?

A. From what I have read, yes.

Q. And everything you've said about the state of the art and everything else at Casa Grande is based on what you've read; right?

A. I've never said the factory is state of the art.

Q. I'm -- yes. You said quite the contrary; right?
A. I believe I said that it -- I didn't agree with that statement.
Q. Right. You don't agree that it's state of the art.
A. No.
Q. I'm sorry. I guess I'm interjecting too many negatives. Do you think that the Casa Grande facility is state of the art?
A. No.
Q. And that's what you testified. And your testimony about that is built on writing. You've never been to the Casa Grande facility; right?
A. I'd love to go.
Q. So that's no, I've never been to --
A. No, no.
Q. -- the Casa Grande facility?
A. I -- no.
Q. And --
A. That said, I --
Q. I'm sorry. There's no question pending. If there's no question pending, you don't have to talk.
And when -- you've said that the Casa Grande manufacturing process was industry standard; right?
A. Yes.
Q. Okay. Like the Wyeth facility that you supervised until 2007; right?

A. Yes. It's got what's called a straight-through process, and so Wyeth has that process, and so does Abbott.
Q. And you've also observed that the manufacturing process system at Casa Grande is closed and cleaned in place using a validated cleaned-in-place process; is that right?
A. That is -- that is Abbott verbiage that I literally took out of some of the things I saw to put in a report to describe the system.
Q. Okay. So you have written down that -- in a report that you made in a case that the entire system is closed and cleaned in place using a validated cleaned-in-place process, referring to the Abbott Casa Grande process; right?
A. Yes.
Q. You've also said that the Abbott process is low risk for E. sak contamination because the pasteurization step is a verifiable critical control point in the HACCP plan, have you not?
A. Yes.
Q. And you've also said that the -- and you also say that the Abbott powder transfer activity is closed off from the factory environment as equipment is used to transfer powder, not people; is that right?
A. I don't remember if I -- that piece I don't remember.
Q. Okay.
MR. REIDY: Excuse me just a moment, Your Honor.

Q. Let me direct your attention to page 54 at line 18 and down to line 24. Can you read that to yourself, please.
A. Wyeth --
Q. To yourself, not out loud. I'm sorry.
A. Okay.
Q. So you have written in a report that Abbott process is low risk for E. sak contamination because of the pasteurization step which is a verifiable critical control point in the Abbott HACCP plan and because all of the Abbott powder transfer activity is closed off from the factory environment as equipment is used to transfer powder, not people; is that correct? You wrote that in your report?
A. Not in the report that was written for this case.
Q. Right. But you wrote it in a report talking about the Abbott Casa Grande facility; right?
A. It was written comparing --
Q. I'm asking you a question. Did you write that in a report, and were you referring to the Casa Grande facility?
A. Yes.
Q. That's all the question is. Thank you.
Now, with respect to areas of the machinery that are in direct contact during the manufacturing process with the product, did Wyeth test those product contact areas in their environmental testing?
A. Yes.

Q. And how was that testing done?
A. With swabs.
Q. And what was tested?
A. I don't remember.
Q. What parts of the manufacturing process that was in direct contact?
A. I cannot in my memory banks come up with an example where I can tell you we sampled this, this, this, this, this, and that. There was lots of sampling done. We did -- some of that happened, yes.
Q. Okay. And so that was part of the environmental program at Wyeth involving swabbing the environment?
A. It was --
Q. And in that swabbing, product contact areas were swabbed; is that correct?
A. No.
Q. Product contact areas were not swabbed during environmental questions.
A. I'm answering your questions. No, it was not part of the routine environmental sampling program.
Q. Okay. So the product contact areas were tested in some other way, not part of the routine?
A. Yes.
Q. And what part of it was the done? Not part of the routine, but how was it tested?

A. You would take investigative samples if you wanted -- if you had concerns about whether the product was -- the equipment was sanitized to a proper degree or if you're working through a particular problem that you wanted more data on.
Q. And the most important part of testing the facility is the testing of the product -- the product that is expo -- I'm sorry, the parts of the factory where the product is exposed to the factory environment; right?
A. Repeat the question, please.
Q. Pardon me?
A. Repeat the question.
Q. Sure. The most important part of environmental testing is in the high-risk areas where the product is exposed to the factory environment; is that correct?
A. Indirectly correct. The -- you want to focus most of your environmental sampling efforts in your high-risk areas.
Q. And your high-risk areas where the product has contact are more important than your -- let me strike that.
Your high-risk areas can include an entire building; right?
A. No, sir.
Q. So if there's a dryer building, is that a high-risk area?
A. I'm trying to answer your questions. What's your question, please?
Q. If -- my question is if there's a dryer building, is that a

high-risk area?
A. Yes.
Q. Okay. And so the testing in a building where there is high risk is more important than a building where there's low risk; right?
A. It's not a question of importance. Usually you've got a finite number of swabs you want to take, so you would take more in the high-risk areas and fewer in the low-risk areas.
Q. And the most important area for assessing risk is the area where product is exposed to the factory environment; right?
A. That is correct.
Q. I'm sorry. Okay. And so the Casa Grande facility, did you review the product contact testing that Abbott had done of its areas where there's product contact?
A. I'm sure I looked at -- of all the data I looked at that, there was some -- that there would have been that information in there as well.
Q. And the Kunkel can of powdered infant formula was manufactured in January of 2008?
A. Correct.
Q. And did you examine, therefore, the environmental monitoring in the /// zone for -- in product contact areas for the fourth quarter of 2007?
A. Again, like I say, I'm working off of memory here. For the report that I did, I summarized the data relative to the date of

manufacture, so I'm sure I undoubtedly reviewed it. I don't remember it.

Q. Okay. So I'm going to put up Exhibit 1015. So I've put up on the screen a environmental monitoring quarterly dryer swab monitoring in the /// zone. Do you see that?

A. Yes.

Q. And do you see the column that says / results?

A. Yes.

Q. And you see that --

MR. REIDY: I'm sorry. This is an exhibit, Your Honor. I meant to take the blackout off for the ladies and gentlemen of the jury.

THE COURT: Are we having a projector problem?

THE CLERK: Same problem.

MR. REIDY: I apologize, Your Honor.

THE COURT: No, it's not your fault. We had a problem early this morning when we were testing the equipment, and we wound up replacing the bulb in the projector. And apparently we're having the same problem now.

MR. REIDY: While we're doing this, Judge, I think I can go on and sort of get the witness to describe what I'm talking about, and then the jury will eventually have this exhibit.

THE COURT: Okay. Thank you. If you're willing to proceed, we appreciate that.

MR. REIDY: I think we can do that because it is working on his monitor.

BY MR. REIDY:

Q. This product contact testing -- I'm sorry. This report looks at areas of testing that include areas that are in direct contact with the product; right?

A. That's correct.

Q. For example, on the left side where it says the column is called sampling location; is that right?

A. Correct.

Q. And the first one says ////////////, right?

A. Yes.

Q. And the next one says ////////////////////

A. Yes.

Q. And then there's another ////////////////////, several more of those?

A. Yes.

Q. And then there's the ////////////////////

A. Yes.

Q. And can you tell the ladies and gentlemen of the jury what role the //////, plays in the dryer?

A. That would be the piece that's like the top of a garden hose and it would spray the mix into the dryer.

Q. So it sprays the liquid mix into the dryer so that it can be dried into powder; is that right?

A. Yes.
Q. And then it has a column for sample by date and time, hours; is that right?
A. Yes, it does.
Q. And it bears the initials of the sampler purportedly?
A. It has initials.
Q. Okay. And it has a date and a time?
A. It does.
Q. And then there's four columns. The first column is SMA control number. Do you see that?
A. Can you make it a little bigger?
Q. You see after -- the third column is called [illegible]?
A. Yes. Okay.
Q. And do you know what [illegible] stands for?
A. It was the name of one of Wyeth's products.
Q. Okay. And so you don't know what this [illegible] stands for since they're presumably not inspecting for Wyeth products in their [illegible].
A. Help me out here. I don't know what the acronym is for.
Q. Okay. I'm just asking if you knew. You don't know it stands for salmonella, for example.
A. I told you I don't know.
Q. Okay. And the next one says [illegible]; is that right?
A. That's correct.

Q. And then the next one says ///, results?
A. Correct.
Q. And then ///, results; right?
A. Correct.
Q. And then the ///, results are zero; is that right?
A. That's correct.
Q. Okay. Let me show you the next page. We won't go through all these, but the next page, it's the same quarter, the fourth quarter of 2007. Do you see that at the top?
A. Yes.
Q. And it lists some additional parts of the product contact equipment in the process; is that right?
A. That's correct.
Q. And the first one it says is the ////////////////////////// //////?
A. Yes.
Q. And then the ////////////////////////////////// -- or W, E, and S; is that right? You're supposed to circle one?
A. Yes.
Q. And then the ////////////////////////////////?
A. Yes.
Q. Okay. And it goes on to list several others; is that right?
A. Oh, yes.
Q. And the ///, result test for all those is also zero; right?

A. Correct.
Q. And in your reading about things with respect to finished product testing and et cetera, did you learn that Abbott has zero tolerance for E. sak in its finished product?
A. I don't know if I ever saw that in Abbott language, but I would understand that that would be the case since they know that that should be the case.
Q. Thank you.
A. I'm not arguing that point.
Q. Now, Abbott had a -- two presumptive positives in its drain in January of 2008 in the dryer building; right?
A. That's correct.
Q. And you've never been in the dryer building; right?
A. Not that specific dryer building, no.
Q. Okay. And you do know that the dryer building itself, that the area of this drain is in an area where the process is nearby, but it's inside stainless steel. Do you know that?
A. How can I know that? I haven't visited the factory.
Q. Okay. I didn't know whether you'd read some of the depositions where that's described or anything else. You don't have any knowledge about where it's located then.
A. As I said, my knowledge from reading the depositions, they were so difficult to read and it was so difficult to obtain any meaningful information from them that I went back and looked at records, and in this particular case describing what a dryer

tower's like is not a need to me since I've been in so many of them and I've been in so many that have dryers of the same brand.

Q. So I'm not saying you should know these things. If you don't know, you don't know. All you have to do is say I don't know.

A. I don't know.

Q. Thank you. And so you don't know whether or not there's any open product area -- open product area anywhere near this drain; right?

A. Open pr -- no, I don't know.

Q. Okay.

A. I have not personally -- you haven't --

Q. Fine. I don't know. That's fine.

Now, when Abbott tested the drain, they had two ///// that tested drains //////// that came back with presumptive positives for E. sak; is that right?

A. That's correct.

Q. And you know that they treated that as a presumptive positive and did further testing; right?

A. That's what the paperwork indicated.

Q. And the further testing that they did was on the ////// //////////; right?

A. I -- that's -- the further testing will be addressed by someone else. I'm familiar with what happened on the ////

Q. Okay. Do you know whether or not there was further testing?
A. Yes, I do.
Q. And do you know that the further testing was negative for E. sak?
A. I believe there's some disagreement about that.
Q. Well, did you see anything that suggested that the subsequent testing was --
A. I'm trying to tell you that in this particular case that will be addressed by my wife when she testifies.
Q. The methodology of doing testing for E. sak that is presumptive and then furthermore specific testing to confirm whether or not it's E. sak, that's a methodology you understand; right?
A. I understand. However, this is an environmental sample. Normal -- normally you -- from an operational point of view, you would just look at the positive as being real and take action accordingly. The idea of treating a environmental sample as something you have to test away is -- well, it's both not appropriate from a laboratory -- good laboratory practice piece, and it's not useful in trying to control the hazard.
Q. And do you know what action Abbott took as a result of the presumptive positive in those two drains?
A. I didn't see any paperwork anywhere that indicated they did anything.

Q. So you don't know whether they went out and immediately cleaned those drains using, you know, stringent chemicals in a way that would kill all the bacteria that was in those two drains?
A. Well, it's kind of too late because they were there. You're making product, so -- and how long have they been there? I mean, it's like you gotta go to the last point it was sanitized.
Q. I'm asking you a simple question. Do you know whether Abbott took the immediate action of thoroughly cleaning the two drains right after they got the presumptive positive?
A. No.
Q. That would be appropriate action; right?
A. That would be one of several kinds of appropriate action.
Q. And the notion of having presumptive positives and then confirming them by more specific tests is something that Wyeth did in its finished product testing; right?
A. Yes, we did.
Q. Okay. And so in Wyeth's testing, Wyeth would test for the EB family in its finished product, and if it got a positive, it would then further check using a more specific test to find out whether it was E. sak; right?
A. That's correct.
Q. And if it was confirmed not to be E. sak, Wyeth shipped the product; right?

A. I don't believe we ever had an instance where that occurred. To tell you the truth, we would likely have not rejected a product out of due diligence.
Q. Okay. So you wouldn't have rejected it.
A. We would have rejected it.
Q. So are you saying that ever occurred?
A. I c -- my recollection is that every instance where we sent something out for genetic analysis came back as E. sak.
Q. In your finished product testing.
A. In our finished product testing.
Q. And do you remember any better how often that happened, by the way?
A. No, I don't. It was rare.
Q. So you never -- your protocol called for testing for presumptive positive and then referring out for the more specific identification of E. sak species, and in every occasion that you recall when you did that your specific test came back positive for E. sak.
A. That's correct. And we're talking about finished product testing, not environmental testing.
Q. Correct. And finished product testing is pretty darn important testing; right?
A. It's compliance testing, yes. Everybody realizes that that's important testing.
Q. Right. And it's compliance testing, but it's also the last

step in making sure that you don't ship product with E. sak in it; right?
A. Yes.
Q. And in the cases you're talking about, it was your final product testing that caused you to find the E. sak that kept you from shipping product that had E. sak in it; right?
A. It's usually more complicated than that, but yes.
Q. In general if you're sampling a finished batch of product, a higher number of samples is better than a lower number of samples; right?
A. Correct.
Q. And how many samples was in the protocol that Wyeth used?
A. We took -- I think it was twenty 65-gram samples across one of our lots for a total of -- for a testing weight of 1,332 grams.
Q. And Abbott's normal testing is ////////?
A. That's correct.
Q. And across how many separate samples?
A. They took ////////////////////////// samples.
Q. Okay. So there were ////////////////////////////////////
//
///// is that right?
A. That would be correct except our lots were considerably smaller than the lots that are produced at Casa Grande.
Q. Okay. But as far as the number of samples, the Abbott

number was //

A. Okay. We're talking 20. You're taking 30. That's not 50 percent.

Q. Wyeth took 20. //

//

//////////// Does that all work for you?

A. Seems like we're taking ////////////////////////

Q. But -- okay. That's another way of stating it. ////////

//

//////////// Those are the same numbers; right?

A. And the number -- reason we were focusing on 20 was that's how the FDA had or organized their original field survey, and that had been implemented at Wyeth.

MR. REIDY: Okay. Thank you very much. That's all I have, Your Honor.

THE COURT: Thank you.

Mr. Rathke?

MR. RATHKE: Thank you, Your Honor. I'll be brief.

THE COURT: Yeah. Well, I don't know about that. I'm very skeptical of claims when lawyers say they're going to be brief. Actually I've kept track for 20 years. And often when a lawyer says, "I just have one more question," the high is 167 additional questions after a lawyer said that, and the statistical mean is 8.8. So brief I guess is in the eye of the beholder. But you may proceed.

REDIRECT EXAMINATION

BY MR. RATHKE:

Q. I have handed you Exhibit 1015 which Mr. Reidy gave you, the fourth quarter 2007 testing.

A. Right.

Q. Correct?

A. That's correct.

Q. And the testing that's reported in that document is testing for //; correct?

A. That's correct.

Q. Is there any testing for E. sak?

A. No.

Q. Mr. Reidy mentioned that there was some corrective action of cleaning when the positives of E. sak were found in the ///// drains. Did you see any indication of that -- of that in the Abbott records that you were provided?

A. No.

Q. In your direct testimony you referred to a stoppage. Do you recall that?

A. Yes.

Q. Is there anything in the record that would indicate that that stoppage was related to an E. sak positive finding in the ///// drain?

A. No.

Q. Is there anything else in the records that Abbott provided

that would indicate that there was any stoppage whatsoever when the ///// drain tested positive?
A. No.
Q. Mr. Reidy referred you to a previous report that you prepared. You recall that testimony?
A. Yes.
Q. When you prepared that previous report, did you have access or had you reviewed any of the Abbott records that were produced in this case?
A. No.
Q. Is there anything or any point that Mr. Reidy raised in his cross-examination which causes you to change any of your observations or conclusions that you made yesterday?
A. No.

MR. RATHKE: Thank you.

THE COURT: Gold star.

Any redirect -- I'm sorry, any recross?

MR. REIDY: Three or less, Judge.

THE COURT: Excellent.

RECROSS-EXAMINATION

BY MR. REIDY:
Q. The questions I asked you about from your prior report were about the temperature and effect of low humidity, that hadn't changed between -- that hadn't changed based on what you read in the Abbott materials, the additional Abbott materials you saw;

right?
A. My conclusion about safety of the --
Q. I'm sorry. I'm asking you only about whether or not any of the weather at Casa Grande had changed because you read more Abbott reports.
A. No.
MR. REIDY: That's all I have. Thanks.
MR. RATHKE: No redirect.
THE COURT: Gold star again.
Okay. You may step down.
And ready to call your next witness?
MR. KING: Jury questions, Your Honor?
THE COURT: Oh, I'm sorry. Yep. Come on back. Thank you. Come on back, Dr. Donnelly. Do the jurors have any questions? Thank you so much for reminding me. Do the jurors have any questions for this witness? Okay. I'm going to wait a minute to see if there are any more. Okay. Doesn't look like it. Thank you. Counsel?
(At sidebar on the record.)
MR. REIDY: It asks for his opinion about whether my client would ship adulterated product, Judge. This witness hates everything about us, and he has no basis for such an opinion.
THE COURT: I agree. Sustained.
(The sidebar was concluded.)

THE COURT: We appreciate the question, but for legal reasons, we're not able to ask it, but we appreciate it nonetheless.

You may step down now. Thank you.

Ready to call your next witness?

MR. RATHKE: Yes, I am, Your Honor. Catherine Donnelly.

THE COURT: Good morning. Would you raise your right hand, please.

CATHERINE DONNELLY, PLAINTIFF'S WITNESS, SWORN

THE COURT: Thank you. Please be seated in the witness box. And you can adjust the chair and the microphones so you can speak directly into the microphones. And would you please tell us your name and spell your last name, please.

THE WITNESS: Yes. My name is Catherine Donnelly, D-o-n-n-e-l-l-y.

THE COURT: Amazing. Spelled just like your husband.

THE WITNESS: What a coincidence.

THE COURT: Really. Okay. The questions might get a little tougher now.

Counsel?

DIRECT EXAMINATION

BY MR. RATHKE:

Q. Where do you live?

A. I live in Burlington, Vermont.

Q. And what's your current employment?
A. I am a full professor at the University of Vermont.
Q. And how long have you been with the faculty?
A. Well, my children would say since the dinosaurs roamed the earth, but 31 years.
Q. What are you a full professor in at the university?
A. I'm in the department of nutrition and food science trained as a food microbiologist.
Q. Could you state your educational background.
A. I received my bachelor's degree in 1978 from the University of Vermont, and then I went to North Carolina State University where I received a master's in food science in 1980 followed by a Ph.D. in 1983.
Q. What has been the principal focus of your research?
A. Most of my research has focused on an organism called listeria monocytogenes. It's a bacterium. I developed testing methods that are used now by the U.S.D.A. for all of the meat testing in the United States. UVM broth is something I developed. I've also done a lot of work looking at the microbial ecology of listeria, and I'm very interested in a topic called sublethal injury, how we improve detection methods to detect this pathogen.
Q. Have you worked with the government?
A. Yes, I have. I've managed grant panels. I was appointed twice by President Clinton and once by President Bush to the

National Advisory Committee for the Microbial -- what is it? National Advisory Committee, Microbial Safety of Food. It's an advisory committee that advises U.S.D.A., the Centers For Disease Control, and the FDA on food safety policy.

Q. Could you briefly describe any honors or special recognition that you've received.

A. In 2006 I was awarded the Maurice Weber Laboratorian Award for the food safety laboratory efforts that I've been engaged in. And I was recently made a fellow of the Institute of Food Technologists.

Q. Why are you involved in this case?

A. I was asked to examine records, plant records, deposition transcripts, and other records relevant to this case.

Q. And you were asked to do so by Lommen Abdo, my law firm?

A. That is correct.

Q. And what conclusions -- or what was your task in reviewing these records?

A. So my task was to go through the documents and deposition transcripts and other records so that I could have opinions in this case.

Q. Relating to what? Opinions relating to what?

A. Well, my opinions relating to whether the Similac NeoSure involved in this case could have been contaminated with enterobacter sakazakii.

Q. And how are you compensated for this engagement?

A. I'm paid by the hour.
Q. Are you occasionally hired for legal cases to serve as an expert?
A. Yes, I am.
Q. What percentage of your income comes from those types of engagements?
A. It varies by year, but I'd say on average about 10 percent.
Q. What materials have you reviewed in connection with this case?
A. So again, deposition transcripts, lot of Abbott records. The documentation in this case is pretty extensive.
Q. Have you reviewed sufficient materials to reach any conclusions?
A. Yes, I have.
Q. And the conclusions and opinions that you have, are those to a reasonable degree of scientific certainty?
A. Yes, they are.
Q. And what is your core opinion in this case?
A. So my core opinion is it's more probable than not that the Similac NeoSure was contaminated with enterobacter sakazakii that was consumed by Jeanine Kunkel.
Q. On what evidence do you base this opinion?
A. Well, the first opinion that I had is the plant conditions at the time that the batch in question was processed presented a very high risk for enterobacter sakazakii contamination.

MR. RATHKE: Your Honor, at this point we would put stuff on the screen. I'm wondering how that's progressed.

THE COURT: Oh. Whether it's working or not? Oh, it's not.

MR. RATHKE: Okay.

BY MR. RATHKE:

Q. Do you have your slides with you?

A. I do.

Q. All right. From the slide that we would put up, could you tell me when the batch which Jeanine consumed, when that was manufactured.

A. So that was batch processed on January 8, 2008, and it was dried on January 10, 2008. And then there was filling of part of the batch on January 10 that went into -- it finished filling on the 11th. And then batch 61281RE10 started filling on January 11 and finished filling later that day.

Q. Did you find anything significant in Abbott's testing results with respect to the environment?

A. On the very day that Jeanine's batch was batch processed, there were environmental results from the plant, and two ///// drain samples, ///// drains ////////, tested positive for enterobacter sakazakii using ////// method.

Q. What is the significance of that finding?

A. So that places this pathogen of concern in the dryer tower the very day that that batch was produced.

Q. In addition to those findings, did you find any other places in the plant where there was evidence of contamination?
A. Yes, I did.
Q. Keeping in mind that the jury doesn't get to see what you're looking at, could you describe those places?
A. Sure. So there's an environmental monitoring report that was produced by Kerri Wade about plant information, and it's important --
Q. Who is Kerri Wade identified as?
A. She works for Abbott.
MR. PERSONS: Matt?
THE CLERK: It's stuck on blackout right now.
THE COURT: So you have to show it to her. Come on. Let's go. Adjust.
MR. RATHKE: We provided the slides yesterday.
MR. REIDY: Your Honor, I'm sorry. I'd just ask that it be put on the screen so that you and the lawyers could see it because it's -- oh, it doesn't work? Okay. It is working.
THE CLERK: You can put it on the screen to show the monitors. It just won't go on this big screen.
THE COURT: Right. But that's all Mr. Reidy's asking for.
MR. REIDY: That's all I asked.
MR. RATHKE: Pat, could you put that on?
MR. PERSONS: Just a moment. Sorry.

MR. REIDY: I'm not asking that we pause while this gets done, Judge. I'm sure it will happen in the next few minutes. That'd be fine.

THE COURT: Okay.

MR. REIDY: Thank you.

BY MR. RATHKE:

Q. So I was asking you about other environmental findings on or about that date other than the two that you've already described.

A. Right. So Abbott establishes very stringent microbiological criteria in its processing environment to minimize the risk for contamination of product. And the criteria that they establish are for a [illegible] The standard that they establish for sites that they test is [illegible].

When I went and looked at the production records, there were several sites in the plant that greatly exceeded the standard. [illegible]

[illegible].

Q. When you use those numbers, what are you referring to, like [illegible]?

[illegible].

Q. And where did you get these findings?

A. These are from Abbott's own records. There were three different documents that I reviewed to compile this data.

Q. How did Abbott report this data?

A. They reported the data differently.

MR. RATHKE: 66, page 12. We'll try to get that up. 66, 12.

MR. PERSONS: I'm not getting a feed to your equipment, Matt.

Q. All right. Go ahead and tell us how Abbott reported this data from Exhibit 66, page 12.

A. So the report was 8 environmental monitoring sites. Floors and drains were sampled for [illegible] on January 8, 2008. Results exceeded action levels and were reported on January 9, 2008. E. sakazakii follow-up testing was completed on January 10, 2008. All results were negative [illegible] acceptably concluding corrective action on January 10, 2008.

Q. And what you've read to us is an exact quote from Exhibit 66, page 12?

A. That's correct.
Q. Is -- that statement that you just read in the Abbott record, is that a correct statement?
A. No, it's not.
Q. What -- what is incorrect about it?
A. They neglected to include results for [redacted] in that report.
Q. And what did they -- what did those show?
A. Those showed [redacted] results for enterobacter sakazakii.
Q. Now, those drains are in what zone of the Abbott factory?
A. They're in the critical [redacted] zone where Abbott has established very stringent microbiological criteria.
Q. Going back to Exhibit 66, page 12, is there a place there for additional information?
A. Yes, there is.
Q. And that's on the form itself; correct?
A. That's correct.
Q. What does it say in additional information? Could you read it to the jury?
A. There is no negative impact to quality due to acceptable [redacted] results, [redacted].

Q. And that's the end of the quote?
A. That's correct.
Q. Did you see anything that you would question about that statement by Abbott in -- on Exhibit 66, page 12?
A. There's no reference to the fact that 6 of these 8 sites greatly exceeded Abbott's microbiological criteria and had more than ////////.
Q. Anything else that you feel should have been included under additional information?
A. They certainly should have included information on /////, ////////////// that tested positive for //////////, ////////.
Q. Did you find any problems or concerns with Abbott's responsibility to these findings?
A. The response was that there was no corrective action. The condition that was unacceptable by their own standards remained, and nothing was done.
Q. And does it say that on that page, that no corrective action was necessary?
A. That's correct.
Q. And it states there on that page that there is no negative impact to quality; is that --
A. That is correct.
Q. And what is your response to that statement?
A. Again, the need for corrective action was very apparent

based on the microbiological data.
Q. According to Abbott's own standards and operating procedures, what is it supposed to do if the amount of bacteria tested exceeds their own action criteria?
A. They need to take corrective action. That could include stopping production and engage in immediate clean-up and retesting to verify that the environmental is back to that ///// ///////// standard that they've established.
Q. Did you see any evidence of that?
A. No, I did not.
Q. Did you see any evidence of any cleaning whatsoever in the Abbott records?
A. I did not.
Q. Did you see any evidence of any stoppage of the manufacturing process of that particular batch?
A. I did not.
Q. Again, staying on Exhibit 66, page 12, what do the Abbott records say about the completion of corrective action?
A. Abbott indicated that their corrective action was completed on January 10, 2008.
Q. Is there anything that -- is there anywhere that it states what the corrective action was?
A. No, there is not.
Q. Should that be in the record?
A. Yes.

Q. When were the -- were there retests that are noted in the Exhibit 66, page 12?
A. Yes.
Q. What does that indicate?
A. Let's see.
Q. Do you have 66, 12 in front of you?
A. I don't. Thank you. It says on this record the retest reports were not completed until June 10, 2008. The report should have been completed and EM documents reviewed for completion and compliance by February 10, 2008.
Q. And what is the significance of that?
A. Well, the significance is no one was paying attention to this critical environmental data.
Q. During its complaint investigation of the Jeanine Kunkel illness, did Abbott review these records?
A. Not the environmental records.
Q. Was there any reference to the E. sak positive finding in the batch review that Abbott conducted after Jeanine became ill?
A. No, there was not.
Q. Do you agree with the results of Abbott's investigation?
A. No, I do not.
Q. What is your conclusion?
A. Well, my conclusion is they certainly -- I can read what they concluded in their report. There were no unusual circumstances surrounding production of this batch. The batch

records showed finished product micro testing results were acceptable. The E. sakazakii test result was negative.

Q. You're quoting from the Abbott records?

A. Yes, I am.

Q. And do you agree with that conclusion?

A. No, I don't.

Q. Could you tell the jury about your disagreement.

A. So they looked at their finished product testing records, but they didn't consider the environmental conditions which were in that plant at the time that that batch was recorded, and those certainly should have been considered. And they did point to problems in the plant at the very time that batch was produced.

Q. Did you review the written procedures for Abbott's monitoring results?

A. Yes, I did.

Q. And when are data records supposed to be checked and reviewed?

A. For completion accuracy and results by the tenth working day of the following month.

Q. Why did Abbott at its Casa Grande plant establish an environmental monitoring program?

A. Their records indicate to help evaluate the cleaning effectiveness as well as the general environmental conditions existing in the production area. In the critical /// zone /////

Abbott established these stringent microbiological criteria, given how close these sites were to the finished product as it was being dried.

And on January 8, 2008, the day that the batch in question was produced, 9 sites exceeded the action levels with 5 cites showing including critical drain samples.

Q. Okay. I'd like to show you Exhibit 66 at page 15. Would you identify that document.

A. Yes. So these are from the dryer -- one of the drain samples that tested positive.

Q. Since the jury can't see it right now, could you describe the document to them.

A. So the document has -- it's basically a printout when you run the . It shows some and it has sample results.

Q. And what are the results? What does it say on the document?

A. It says drain , positive for the target enterobacter sakazakii.

Q. And then showing you Exhibit 66, page 18, would you first identify that document?

A. Again, this is a of results from , and it indicates that it is positive for

////////.

Q. And what is the date of those results?

A. The time of analysis is January 10, 2008.

Q. Now, what is the industry -- or the microbiological standard when you get a positive result?

A. Well, this is definitely a ////////// result indicating the presence of enterobacter sakazakii in that ///// drain sample that was collected by Abbott personnel.

Q. You're familiar with United States v. Barr, B-a-r-r?

A. Yes, I am.

Q. And that was a court decision out of New Jersey?

A. That's correct.

Q. Did that court decision have any impact on the microbiological community?

MS. GHEZZI: Objection, Your Honor. Calls for a legal conclusion from this witness. Commenting on a court case.

THE COURT: Doesn't call for a legal conclusion. It's overruled.

BY MR. RATHKE:

Q. Go ahead.

A. So the United States versus Barr was a case that --

Q. I don't -- I don't want you to describe the case. I want you to describe its impact on the microbiological community.

A. Sure. So it established standards for the pharmaceutical industry that basically said if you run a test and you get a

positive result, you stick with that positive result. You can do follow-up testing and get a different result. But you have to weigh the value of the positive as well as any follow-up result that might be different.

Q. And what do the records show, the Abbott records show, about the follow-up testing in Columbus, Ohio? And that would be -- here. Let me show you -- Exhibit 66, page 16.

A. So once Abbott received the positive results from [redacted], they took samples [redacted] for confirmation as enterobacter sakazakii or not.

Q. What do the Abbott written procedures state should be done in that kind of a situation?

A. So basically what I just described. [redacted].

Q. What is your conclusion about Abbott's follow-up testing?

A. So the results of that testing, they show -- it says [redacted] on Casa Grande environmental isolates received January 14, 2008. Results are as follows. They don't show [redacted] But they say for site [redacted] drain [redacted] results are not enterobacter sakazakii. For [redacted]

drain [redacted], the results are not enterobacter sakazakii.

Q. I want you to explain a little bit more detail how that follow-up test differs and -- differs from the first test. And I think where we should start is we should start by describing the [redacted]

A. Sure.

Q. It's [redacted] correct?

A. Yeah, [redacted].

[redacted]

Q. And that was the defect in terms of how the sample was prepared for the follow-up testing.

A. That's correct.

Q. And you described the deficiencies in that procedure.

A. That's correct.

Q. So now -- what did Abbott then -- how did Abbott test the samples that it got [redacted]?

A. From [redacted]? From the [redacted] environmental isolates?

Q. Yes.

A. Right. [redacted]

Q. And that's what showed the negative result?

A. That's correct.

Q. Did they -- given what they were provided, are there any defects in the manner in which they did [redacted]

[illegible]?
A. I wouldn't know that because this is simply a report reporting end results. There is no provision of actual data output from those [illegible] results [illegible].
Q. When [illegible] is done, are there normally confirmatory documents?
A. Yes, there are.
Q. What kind of -- what kind of documents?
[illegible].
They identify something. We haven't been provided with what that identification was.
Q. And all we have is the result?
A. That's correct.
Q. Now let's go to the finished product testing on this batch. Abbott tested its finished product of this batch and concluded the lot was acceptable due to negative E. sak results. What are

the problems with Abbott's finished product testing?
A. So for finished product testing, Abbott failed to include a very essential critical component. The FDA specifies that when you're analyzing a product like a powder where the product has been subjected to drying, any organisms present in that powder might be injured from that drying. And so you have to go through a nonselective preenrichment.
Q. What do you mean by nonselective?
A. So nonselective me -- and what the FDA specifies is in distilled water, pure water with nothing added so that you're giving organisms in there that might have been injured by the drying process a chance to repair any damage before you then go into selective enrichment in medium that contains chemicals that specifically select for your target, enterobacter sakazakii, and suppress the growth of organisms that wouldn't be enterobacter sakazakii.
Q. All right. So what was the problem with the way that Abbott did this process?
[illegible].
Q. So how would that impair their ability to get accurate results?
A. Any organisms that were injured as a result of the drying process would not be able to grow [illegible]

[redacted].

Q. And Abbott's procedure, was it adequately described in the document you received from Abbott?

A. Yes.

Q. Did you also get a chance to read Dr. Martin Wiedmann's, Abbott's expert's -- read his report?

A. Yes, I did.

Q. And did he confirm the methodology that Abbott used?

A. Yes, he did.

Q. So what's the conclusion -- and I think we'd be putting up slide 13. What is the conclusion that you have reached with respect to the finished product testing procedure that Abbott employed?

A. My conclusion is I can't have confidence in their negative results of finished product testing for enterobacter sakazakii because the methods that they used significantly underestimate the presence of enterobacter sakazakii.

Q. Could you look at slide 14. What do Abbott's methods specify?

A. Abbott's methods specify that [redacted].

MS. GHEZZI: Excuse me, Your Honor. What slide? What are we on?

MR. RATHKE: Fourteen.

MS. GHEZZI: Can you show it to me? Your slides weren't numbered.

Q. In your opinion what's the problem with that?

[redacted].

Q. Do you recognize the name Suzanne Roison, R-o-i-s-o-n?

A. Yes, I do.

Q. And who is she?

A. She is Abbott's vice president of manufacturing.

Q. And has she recently been quoted in an article on Abbott's web page about the importance of controlling bacteria?

A. Yes.

Q. Would you read the quote that Abbott's vice president of manufacture -- manufacturing stated about environmental testing?

A. She stated, "If we can prevent bacteria on the floor of areas outside production, we can keep it from coming into the processing area. It's all about prevention."

MR. RATHKE: Thank you. I have nothing further.

THE COURT: Why doesn't everybody take a stretch break before the cross-examination.

MS. GHEZZI: Your Honor, can we use an easel?

THE COURT: Pardon me?

MS. GHEZZI: Can we use an easel, a flip chart?

THE COURT: Sure. Please be seated. I did want to explain we've had very, very few technology glitches in the nearly 15 or so years we've had a high-tech courtroom. But the sequester has really hurt the federal courts. We used to have two full-time technology people here in Sioux City who were very, very experienced, had been with the court for a long time.

We're down to one brand new person who really doesn't -- she's just in training. It's not her fault.

I have e-mailed our clerk of court in Cedar Rapids, and they're sending over the most experienced tech person we have. And it's related to the problem we had yesterday which we were able to fix. And on the break we're going to try and fix it. But we may not be able to fix it. And so you'll just have to bear with us. But we're trying as hard as we can to get the technology back.

MS. GHEZZI: Your Honor, we're having a little problem having the thing stay up on the easel but . . .

Will this work like this? Can you hear me?

THE REPORTER: Perfect. Thank you.

CROSS-EXAMINATION

BY MS. GHEZZI:

Q. Good morning, Mrs. Donnelly -- or Dr. Donnelly.

A. Good morning.
Q. We've met before.
A. Yeah.
Q. Yeah. Dr. Donnelly, you're not an expert in infant formula manufacturing plant design, are you?
A. No.
Q. And you've never participated in the manufacture of powdered infant formula?
A. That's correct.
Q. And you've never worked in a factory.
A. That's correct.
Q. Okay.
THE COURT: Dr. Donnelly, can you slide that one microphone a little closer? Yeah. When you turn sideways like that, that one moves, so you can kind of turn it with you.
THE WITNESS: Great.
THE COURT: Okay?
THE WITNESS: Perfect. Thank you.
THE COURT: Thanks.
BY MS. GHEZZI:
Q. And you've never designed a bacteria-free powdered infant formula, have you?
A. I have not.
Q. And you never participated in any governmental efforts regarding E. sakazakii; right?

A. That's correct. The only thing I did, I was on the National Advisory Committee For the Microbial Criteria For Food at a time when we were actively discussing E. sak as a problem in powdered infant formula.
Q. Right. But other than you being present for -- my recollection was you weren't present for any discussions on E. sakazakii. You were just on the -- you were involved in it at the time that that was happening; is that correct?
A. And there were active discussions about enterobacter sakazakii on that committee.
Q. Okay. And you've never participated in the investigation of an infant's E. sak illness; right?
A. I have not.
Q. And you've never designed a finished product testing protocol for powdered infant formula?
A. I have not.
Q. Or for an E. sak-specific testing protocol for powdered infant formula.
A. That's correct.
Q. And you've never designed an E. sak environmental testing protocol for a powdered infant formula facility.
A. That's correct.
Q. And you've never isolated E. sak from any powdered infant formula yourself.
A. I have not.

Q. And I don't believe -- but correct me if I'm wrong -- you've never seen E. sak under a microscope, have you?
A. I'm sure I've seen it under a microscope. I've been looking at dairy products for years and years, and it's part of the normal flora.
Q. Yeah. And your expertise is in cheeses; correct?
A. That's part of my expertise.
Q. Okay.
A. My expertise is related to listeria.
Q. Right.
A. That is in almost everything.
Q. Yeah. Now, you reviewed -- you reviewed the testing records that were done in connection with the FDA and the CDC investigation of this particular illness event; right?
A. Yes, I did.
Q. And you would agree with me that neither the FDA nor the CDC isolated any E. sak in the powdered infant formula cans that they tested; correct?
A. That's correct.
Q. And one of those cans was the very can that was fed to -- the powder from which Jeanine Kunkel was fed.
A. That's correct.
Q. Okay. And by the way, you talked about chromogenic media. Both the FDA's method when they tested this, their product -- I mean -- strike that.

Both the FDA and the CDC when they tested the Abbott NeoSure product in 2008 connected with this investigation, they used chromogenic media, didn't they?

A. They did, that's correct.

Q. Okay. And using chromogenic media, they found no E. sak in any of those cans of formula; right?

A. That's correct.

Q. And you reviewed Abbott's finished product testing in this case as you discussed with Mr. Rathke moments ago; right?

A. Yes, I did.

Q. And you are aware that Abbott used a random stratified sampling method for its finished product testing; correct?

A. Yes, I am.

Q. Okay. And that is the very method that is discussed in the Jongenburger article that you referred to in your report to support your opinions in this case; correct?

A. That's correct.

Q. Have you ever performed a ////////// test on an E. sakazakii suspected isolate?

A. Not on E. sak.

Q. Not on E. sak, okay. But you know what the ////// is supposed to look like; correct?

A. That's correct.

Q. And when you were testifying for Mr. Rathke, you went down the items -- I don't know if you have a copy of it there -- the

items that are on this piece of paper; right?
A. Yes.
Q. And the first one says --
MR. RATHKE: It's Exhibit 66, page 12.
MS. GHEZZI: Yes.
Q. -- ///// drain /; right?
A. That's correct.
Q. Okay. Let's talk about ///// drain /. Do you know where ///// drain / is in the Abbott facility at Casa Grande?
A. No, I don't.
Q. Okay. The only thing you can tell is that it is in a floor, correct, or do you even know that?
A. I don't even know that.
Q. Don't even know that, okay. So the jury can understand a little bit about this and what it should look like and I want you to be able to see it, when you get a ///////// it looks -- ////////////////// correct?
A. That's correct.
Q. Can you see this?
A. Not really.
Q. I'm sorry. Everybody see it?
MS. GHEZZI: Judge, can you see it?
THE COURT: I don't need to.
MS. GHEZZI: Okay. Can everybody see it? Okay.
Q. And what happens when you do a ////////////////////,

[illegible]?
A. There's an internal control [illegible]
Q. And an internal control [illegible] right?
A. Correct.
Q. And on the printout that you get, the true positive E. sak looks like this; right? You have it right there. See that?
A. That's an internal standard.
Q. Yes. That's an internal standard, and that shows what the control is in [illegible] correct?
A. To show that the test is running correctly.
Q. Yeah. That's what the E. sak is going to look like. Now, for [illegible] drain [illegible], it looked like this, didn't it? Can you see it?
A. I'll take your word for it. These aren't [illegible] drain [illegible] samples in front of me.
Q. Let me hand you one.
A. Yep.
Q. Did you look at that before you came in here today?
A. Not -- when I reviewed the records, I saw that.
Q. Now, if this is what -- first of all, if this were to be a real E. sak, it should look like this, shouldn't it? Do you

know that?
A. It doesn't look like that.
Q. Do you know that that's what it should look like?
A. I know what the ////////////////////////////////////
////////////////////.
Q. And if you look on what's in front of you, do you see the little portion on the bottom underneath the ////////////////
//
//
////////////////////?
A. Yes, I do.
Q. Okay. And actually if there's an E. sak present, it should actually ////////////// -- ////////////////////////////
//
//
////////////////////////////////?
A. That -- what you've explained isn't correct.
Q. Okay. Well, that's your opinion; right?
A. That's my opinion.
Q. Okay. But you've never done ////////////////,
A. Not for E. sak, no.
Q. Okay. And when you look at that for /////, drain /, with that little squiggly over here ////////////////////////////
////, if you were looking at that in a laboratory, would it be your opinion that that was E. sak?

A. My opinion would rely on ////// concluded.
Q. Okay. And let's take a look at ////// concluded. What did /// conclude for ///// drain /?
A. For ///// drain / it says negative for enterobacter sakazakii.
Q. Right. So if there's a ///// drain negative for enterobacter sakazakii, there's no corrective action report required; isn't that correct?
A. As far as enterobacter sakazakii is concerned. If that ///// drain sample had ////////////////////////////////////, ////////////// there's a need for corrective action.
Q. And the corrective action -- the corrective action would be to clean the site, but it doesn't have -- but if it's not E. sak, that has no relationship to your conclusion that there was an E. sak problem in this particular batch, at least for ///// drain /; correct?
A. I don't agree with that. That's not correct.
Q. Okay. Then let's take another one. Let's take your -- sorry. Do you have Exhibit 66, page 12 right there?
A. Yes, I do.
Q. Okay. And did you look at the ////////// for ///// drain // that's second on the list?
A. Yes, I did.
Q. Okay. And what did ////// conclude with respect to the test on // for that particular isolate?

A. That was negative.
Q. That was negative, yeah. And what was the test -- and that one, by the way, was even smaller. That one looked something like that.
A. That's correct.
Q. Right? And that's why it was a negative; right?
A. Yes, ////// reported that as a negative result.
Q. ////////////, And the next one on Exhibit 66, page 12 was ////////////////////, correct?
A. The //////////////////////?
Q. Right. You have no idea where that is, do you, in the Abbott plant?
A. I don't.
Q. And did you look at ////// results for that before you came in here today to testify?
A. Yes, I did.
Q. And what did that show?
A. That's negative.
Q. That's negative.
A. For E. sak ////////////////////.
Q. For E. sak, exactly. And then did you look at the next one which is the ////////////////////////, that's on the floor as well? Did you -- do you know that? Do you know where that is in the plant?
A. I don't, no.

Q. And did you look at that before you came in here today?
A. Yes, I did.
Q. Okay. And that was negative for E. sak as well [redacted].
A. That's correct.
Q. Okay. And the number 5, [redacted], did you look at that before you came in today?
A. Yes, I did.
Q. Okay. And that one was also negative for E. sak [redacted]?
A. That's correct.
Q. Okay. And then the next one is number 6, [redacted] Do you know where that is?
A. I don't.
Q. Okay. Don't know it's on the floor someplace?
A. That's what I would assume.
Q. Okay. And did you look at that [redacted] result before you came in here today?
A. Yes, I did.
Q. And that was negative.
A. That's correct.
Q. For E. sak.
A. For enterobacter sakazakii.
Q. And number 7 is the [redacted]; right?
A. That's correct.
Q. And you don't know where that is.
A. No, I don't.

Q. And did you look at that one before you came in here to testify today?
A. Yes, I did.
Q. Okay. And that result was negative as well; right?
A. That's correct.
Q. And the last one on here is ///// drain //; correct?
A. That's correct.
Q. And you don't know where that floor drain is either, do you, in the Abbott plant?
A. I do not.
Q. No idea. So you have no idea where any of these particular testing sites are with respect to the Abbott equipment that makes powdered infant formula.
A. That's correct.
Q. Now, you're not an expert in Abbott's forms, their manufacturing forms or testing forms that they fill out, are you?
A. No, I'm not.
Q. No. And you looked at -- in the course of looking at ////// /// results, you looked at //////////////////////; right?
A. That's correct.
Q. Because the whole basis for your complaint about what was written on Exhibit 66 that Mr. Rathke read to you was based on the fact that reporting hadn't been done; correct?
A. It -- I didn't file a complaint, and my concern was there

was omission of critical data that showed positive results for enterobacter sakazakii in two [redacted] drain samples.

Q. Well, you were also saying that you were -- you were arguing or you were, I should say, testifying that Miss Wade's statement here that there is no negative impact to quality due to acceptable [redacted], and you said that was terrible, she should never have said that, there was -- there was a negative impact; right?

A. And I don't agree with that because the impact to quality, you have quality criteria and safety criteria. Testing for enterobacter sakazakii is safety criteria. Their hygiene criteria is [redacted]. Six of those eight sites that you just read had [redacted].

Q. Right. That's Abbott's standard; right?

A. That's correct.

Q. And you have no idea where these testing sites are. They're all floors, but you have no idea where they are.

A. That's correct.

Q. If we went outside right now, you and I, and we took a swab outside this courtroom, what would the [redacted] count be? Do you know?

A. I have no idea.
Q. It'd be way over 5,000, wouldn't it?
A. I have no idea.
Q. Okay. You have no idea what it would be.
A. (Witness shook head.)
Q. And so you don't even know in connection with -- well, strike that.

Let me just ask you this. The other thing that you complained about with Exhibit 66, page 12 was that you said the // drains ////////// ///// were not included in this report; right?
A. That's correct.
Q. Okay.

MS. GHEZZI: One moment, Your Honor. Just trying to find it.

Q. Now -- turn the page here. You looked at the ////////// for whatever one I have here, drain ///; right?
A. Yes, I did.
Q. And if we were to draw that on this slide -- ///////////, we've got the -- do you have it in front of you?
A. I do.
Q. Oh, good. Thank you. You've got the control; correct?
A. I don't look at /// results ////////////////////// I look at what the instrument tells me the result is.
Q. Okay. But this is coming off an instrument. Abbott's

not -- Abbott's not creating this ////; right?
A. They're running the analysis. ////////////////////,
/////////.
Q. Yes, yes.
A. And I place confidence in their technology --
Q. Right.
A. -- and what the results are telling me.
Q. That's right. So Abbott didn't make this up.
A. That's correct.//
//, //,
//,
////////; correct?
A. That's correct.
Q. Okay. And so on this particular drain which happens to be drain //, what this looks like is this, something like that. I'm not a great artist. It looks like that; right?
A. Again, that's subjective. I go back to the instrument and its internal standard and whether that ////////////////////, meets their standards for determining --
Q. Dr. Donnelly --
A. -- presence or absence.
Q. Do you have -- excuse me. Do you have this picture in front of you?
A. But that's a --
Q. I'm asking you do you have it in front of you.

A. Yes, I have the picture in front of me.
Q. And does it look like this?
THE COURT: You need to stop interrupting the witness.
MS. GHEZZI: I'm sorry, Your Honor.
THE COURT: That's okay. And she needs to not interrupt you as well.
Q. And does it look like this?
A. Yes, it does.
Q. Thank you. And if I took -- I don't want to waste a lot of time. If I took out the drain -- and I can as soon as I find it. It is page --
MS. GHEZZI: Excuse me, Your Honor. It is important.
?
A. Correct.
Q. Okay. Now let's take drain -- the report for drain . Do you have it there, Dr. Donnelly?
A. I d -- yes, I do.
Q. Okay. And this is handwritten; right?
A. Oh, actually I don't have that in front of me.
Q. Okay. Let's get you one.
MR. RATHKE: What page?
MS. GHEZZI: Seventeen.
Q. Do you have that there?

A. Yes, I do.
Q. Okay. And this shows that the sample date was taken on January 8; right?
A. That's correct.
Q. Okay. Okay. So the sample date is January 8; right?
A. That's correct.
Q. And it says there is a presumptive positive; right?
A. That's correct.
Q. Okay. Because the [redacted] -- it's a screening test; right?
A. It's a test.
Q. Okay. The FDA describes it as a screening test.
A. It can be used as a --
MR. RATHKE: I'm going to object to Miss Ghezzi testifying.
THE COURT: I think she -- if you would let her finish her que -- her whatever it was, it probably would have been a question, but we don't know because you objected before she finished.
MS. GHEZZI: Thank you, Your Honor.
Q. Presumptive -- so the screening test shows a presumptive positive; right?
A. Wrong.
Q. Or it shows a negative; right?
A. It shows a positive or a negative.

Q. And if the FDA disagrees with you, would you stand corrected?
A. I -- they wouldn't disagree with me. The ////////////, ///, you get a result. The way you use that test, Abbott is using it as a screening test. But it's a test, and it gives a result, and the result is either positive or negative for the target.
Q. Okay. Well, I can -- we're going to do the FDA in a little bit. But let's -- and let me just show you this. So you have 66, page 17 in front of you, Dr. Donnelly?
A. Yes, I do.
Q. Okay. And you see where it says about a third of the way down the page E. sakazakii results and it gives a negative and then a presumptive positive, and the Abbott person on January 8 of 2008 circled presumptive positive; right?
A. That's correct.
Q. And then you look down below that, and it says ////////// // // // ////////////////////////// And then it shows E. sakazakii confirmation results, negative. Is corrective action required? And no is circled. There's a reported by whose name we can't read the signature of, and the report date is -- what's the report date there? Can you tell?

A. January 21, 2008.
Q. And according to what you know about Abbott's own protocols, that's an early report on that drain result, isn't it?
A. I don't have an opinion on whether it's early or late. It's when it was run.
Q. You testified this morning that the -- and I'm sorry that I can't get all of your slides in order very quickly here for the jury, and I'm going to try and speed this up but that it had to be done by some time the next month; correct?
A. The tenth working day.
Q. Tenth working day of the next month.
A. That's correct.
Q. Okay. All right. So, you know, January 21 is in the same month as January 8.
A. That's correct.
Q. Right? And it was reported on -- in the paperwork on January 21, 2008; right?
A. That's correct.
Q. So that -- did that escape your notice when you testified this morning?
A. No, it didn't.
Q. No. And what about for the next drain? What about for ///// drain ///?
THE COURT: Before we get to dryer drain 4A, I'm going

to give the jury a mid-morning recess, and we'll be in recess until 10:45.

(The jury exited the courtroom.)

THE COURT: The witness can -- you can step down and remain in the courtroom, but I have a matter I want to take up with the lawyers. Everybody can be seated.

So I don't know when the glitch will be fixed. There's a chance during the break it may be fixed, but we're not sure. We have another option. I personally don't think it's a very good option, but I wanted to disclose it to the lawyers. We could go down and use the first floor courtroom.

Yes, Mr. Rathke?

MR. RATHKE: We have a projector. We just got it from local counsel.

THE COURT: Yeah, that's not --

MR. RATHKE: Would that be an option?

THE COURT: No.

MR. RATHKE: No?

THE COURT: How many lumens is your projector? I guarantee you it's not going to work. I just guarantee it's not going to work. You can try it if you want to on the break. I don't know where you'd set it up to have it work on the screen. And I just don't see it as a viable option. That's a 6,000 lumen projector. Yours is probably 1,800 lumens at the most. It's just not going to work in a big room like this. We

certainly can't put it up there because it doesn't have the throw and it doesn't -- there was originally a $50,000 lens to accommodate the 28-foot throw, so I can't imagine yours is going to work. I don't know where you'd put it. But if you want to screw around with it, you can, but thanks for the interruption. I really appreciate it.

We can use the first floor courtroom. The problem is for well-staffed cases like this one, it only -- it wouldn't work very well because it only has two counsel tables, but it has, you know, reasonably good technology, much different system. It's got what's called a rear projector. We could take that over, but I don't know where all the lawyers would find a place to sit.

Or you can just kind of do it the old-fashioned way which actually might actually speed up the examination and the jurors might actually understand more of it. But it's really up to you.

So you can set up your projector if you want to. But we're going to take ours down and power it back up and see if we can get it working. But I don't have a whole lot of confidence we're not going to continue to have this problem till they can actually isolate what the problem is. So we'll be in recess till 10:45.

(Recess at 10:21 a.m.)

THE COURT: Please be seated for a second. We do have

somebody coming over from Cedar Rapids. Hopefully it's going to be a more permanent fix than these kind of temporary fixes. They're a little bit unsure as to what the exact problem is, but we're going to try a major global fix this evening.

Here's what I'd like to suggest. You know, I hate to suggest it lest you abuse the suggestion. But I'd be willing after the cross-examination when you do your redirect to have you do some limited -- if there's something that's just crucial to your case and you didn't get a chance to show them some slide that you think is actually going to make a difference in the trial, I'll allow you to do that, and then Miss Ghezzi can do recross on it.

MR. RATHKE: Thank you.

THE COURT: Okay? Let's have the jurors brought in.

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

Miss Ghezzi, you may continue with your cross-examination.

MS. GHEZZI: Thank you, Your Honor. I'm going to try and turn this mike on.

BY MS. GHEZZI:

Q. Dr. Donnelly, where we left off was -- I don't know if you have a copy of it. Do you have ///, the report for ///////, the retest report?

A. Is it 66, page 17?

Q. No, no. I'll put it up. And this is -- it's Exhibit 66, page 14. Let me see if I can zoom in even better. Whoa. Okay. And you can see that this is for -- this is a retest report, nonproduct contact, right?

A. Yes.

Q. And right here it says drain ; right?

A. That's correct.

Q. Okay. And then we talked about the presumptive positive. And we saw that the sample date was 1 -- January 8, and then the review date was -- report date was 1-8, and the review date was 1-10, 2008. Let me zoom out a little. And you can see the date -- the negative confirmation, right, and the review date of 1-21-08; correct?

A. Correct.

Q. All right. And for drain , we have the same -- we have the same kind of report. And you see that this is -- the date of this report here is -- drain ; correct?

A. That's correct.

Q. And the sample date is January 8.

A. Correct.

Q. The review date is January 10. You see a negative confirmation, and you see a report date by January 21, 2008; right?

A. Correct.

Q. Okay. And so for drain , when you said that the report

was not done pursuant to the timing in Abbott's protocol, you were incorrect; right?
A. That's correct.
Q. Okay. And then for the others, I'm just going to put one up, representative up, so we don't waste a lot of time. This is -- this is one of the reports -- this is one of the reports that shows a negative E. sak result, right, [redacted]?
A. Correct.
Q. Okay. And that sample date was January 8.
A. Correct.
Q. The report date was January 8, and the review date was January 10; right?
A. That's correct.
Q. Okay. And below that result that says E. sakazakii results it reads [redacted]; right?
A. That's correct.
[redacted]
[redacted]; right?
A. That's correct.
Q. Okay. So there's no reason to do corrective action report, right, at this -- for the E. sak confirmation results, report date 6-10. You see that?
A. That's correct.
Q. Okay. And so when you were testifying this morning about

the plant information report that said that somebody should have completed a report by the next month with respect to the eight negative isolates, that really wasn't -- I mean, it really didn't even need to be done; right? What it was demonstrating was that when Abbott went back and actually did look at its environmental testing it indicated that this report wasn't -- I mean that it wasn't dated, that somebody had re-reviewed it; correct?

A. What I testified was that Abbott's reports needed to be completed by the tenth working day of the next month.

Q. Right.

A. This wasn't reviewed until June. This is only [redacted].

Q. These are the sites that you -- these are the exact sites that you testified to today that exceeded the [redacted] level. These are the exact sites.

A. But those [redacted] results for enterobacter sakazakii. There are separate results for [redacted].

THE COURT: You know, I'm going to strike the last statement by counsel because that's clearly testifying which you have a tendency to do. These are the sites. They're the exact sites.

MS. GHEZZI: Well, I could say --

THE COURT: But you didn't.
MS. GHEZZI: Okay, Your Honor.
THE COURT: Yeah.
MS. GHEZZI: I usually --
THE COURT: And so you have to be careful to ask questions.
MS. GHEZZI: Okay.
BY MS. GHEZZI:
Q. Those are the exact sites, aren't they?
A. That's correct.
Q. Okay?
THE COURT: Excellent.
Q. Okay. Now, you also testified this morning. -- well, let me ask you this. In 2008 the FDA's published recommendation for finished product tested -- testing for powdered infant formula recommended the use of VRBG as media, didn't it?
A. Yes, it did.
Q. And the FDA used that method to test successfully for E. sak, didn't it?
A. There's a question of whether it was successfully. The CDC had issues with the FDA's testing methods.
Q. Well, okay. Do you know what the -- what CODEX thought

about -- I'm sorry. Strike that, Your Honor, please.

Let's talk about the FDA first. And the FDA method in 2008, the recommendation was to test for 333 grams of formula from a batch; right?

A. That's correct.

Q. Right? Okay. And the CODEX recommendation was to test for 300 grams of formula; correct?

A. That's correct.

Q. Okay. And the FDA's recommendation was to use distilled water to preenrich powdered infant formula; right?

A. That's correct.

Q. And the FDA's recommendation also included the use of brilliant green dye, didn't it?

A. For secondary enrichment, yes.

Q. Okay. And the FDA's recommendation was to incubate its

solution overnight; right?
A. Correct.
Q. And overnight is not 24 hours, is it?
A. That's correct.
Q. Okay. And Abbott's manual -- you looked at Abbott's microbiological methods manual, didn't you?
A. Yes, I did.
MS. GHEZZI: 1016, do we have it?
Q. I'm sorry. Did you say you looked at it?
A. Yes, I did.
[redacted]
[redacted].
Q. Let's look at it. This is -- I'm going to leave it like that. Can you see that, Dr. Donnelly?
A. Yes, I can.
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]?

// ////////////.

Q. And you looked at the Cook and Thurber audits in this case; correct?

A. Yes, I did.

Q. All right. And one of the comments in there was in connection with laboratory procedures and documentation it says laboratory -- this is Exhibit 1012A for the record. We may not have to show it. I don't want to -- laboratory procedures are documented, authorized, and dated by the division headquarters. Testing procedures are based on recognized and approved procedures, and documentation of all testing is available, and the rating was excellent. Do you remember reading that?

A. Yes, I do.

Q. Okay. And that was for the audit that ended in 2007; right?

A. Correct.

Q. Okay. And then the audit for 2008 was similar; correct?

A. That's correct.

Q. Okay. And the FDA reviews Abbott's procedures annually during its annual audit. Are you aware of that?

A. Yes, I am.

Q. And that includes its testing procedures and its testing methods and its testing results; correct?

A. Correct.

Q. Okay. And there's no suggestion -- have you seen the FDA

audits in this case, Mrs. Donnelly -- or Dr. Donnelly?
A. I believe I have.
Q. Okay. And there's no suggestion in any of those audit reports that the FDA did that Abbott failed to properly test for E. sak, whether it was finished product or environmental testing; isn't that right?
A. That's correct.
Q. Okay. And there's no suggestion in any FDA audit that you've seen that Abbott failed to validate its E. sak testing methods; correct?
A. That's correct.
Q. Okay. And there's been no suggestion by any third-party auditor that you've seen in this case that Abbott failed to properly test for E. sak in its plant or its finished product; isn't that correct?
A. That's correct.
[illegible]
Q. Okay. You're familiar with the CODEX Alimentarius Code of Hygienic Practice for Powdered Formulae For Infants and Young Children from 2008, are you?
A. Yes, I am.
Q. Okay. And are you aware of the con -- this is Exhibit

1019, page 25. And it says -- I'll just read it to you, and tell me if you remember this -- tracking the level of EB in the processing plant environment is a useful means of verifying effectiveness of the hygienic procedures applied and also allows undertaking corrective actions in a timely manner. Environmental monitoring of EB provides baseline levels and, therefore, allows the tracking of changes over time; correct?

A. Correct.

Q. And in addition to CODEX, the World Health Organization, WHO, the World Health Organization, stated some -- had some comments in its -- in its report on E. sak from 2006. This is Plaintiff's Exhibit 111, page 39. Have you seen that report, Dr. Donnelly?

A. Offhand I don't recall.

Q. I'll show it here to you. And this is what the World Health Organization says in 2006. There is interest in considering enterobacteriaceae as an indicator of process hygiene in the manufacturing environment. Therefore, in addition to estimating the concentration of E. sakazakii in powdered product, it is also necessary to estimate the level of enterobacter -- enterobacteriaceae; correct?

A. Correct.

Q. And that's the World Health Organization in 2006; right?

A. Correct.

[illegible]

Q. Now, I want to talk a little bit about the presumptive positives. I just want to show you now that we have the monitor up what the FDA said.

Okay.

MS. GHEZZI: You know what, Your Honor? I apologize. I don't think that's an exhibit, so can't show it. Sorry.

Q. I can't -- I could show it to you, but we're not going to do the blackout. So I'm just going to ask you if you -- have you seen the Bacteriological Analytical Manual from the FDA from -- that was published in 2012?

A. Yes, I have.

Q. Okay. And here it describes the method that the FDA was using, had used for several years; is that correct?

A. That's correct.

[illegible] --

A. Polymerase chain reaction.

Q. Polymerase chain reaction, all right. And it talks about the PCR portion of the method is a screening method whose

positive results should always be confirmed with a cultural method; correct?

A. Correct.

[illegible]

Q. Okay. Are you aware of the FDA's methods -- Bacterial Analytical Method manual from 2002?

A. Yes, I am.

Q. Okay. And in the portion of it that says typical E. sakazakii colony morphology, VRBG agar, typical colonies will appear as purple colonies surrounded by a purple halo of

precipitated bile acids; right?
A. That's correct.
Q. Correct? Okay. And I think I can put this up because you sent it to me as a demonstrative.
MS. GHEZZI: I'll take the rest of it off that's not, Your Honor.
Q. Is that what E. sakazakii looks like in that medium?
A. Yes, it is.
Q. Okay. They're pretty easy to detect, aren't they? Do you know what you're looking for? Have you seen them before?
A. If it's a mixed culture, you can't tell E. sak from enterobacter cloacae, from any other enterobacteriaceae, the larger group there. They all look the same on that media.
Q. Well, not according to the FDA. That's according to your opinion here today; right?
A. That description that you read from the FDA would apply to enterobacter cloacae as well.
Q. It doesn't say that, though, does it? I can show it to you. I can't show the jury, but I can show you. Right there, do you see that?
A. It describes what E. sak will look like.
Q. Okay.
A. But the problem with VRBGA, it's specific for enterobacteriaceae. There's a lot of organisms that are not E. sak that will appear exactly the same. They'll be reddish

purple colonies.
Q. And you've never done that -- you've never cultured it like the FDA did using the FDA's method, have you?
A. No, I have not.
Q. Okay.
MS. GHEZZI: Nothing further, Your Honor.
THE COURT: Thank you.
Mr. Rathke?
MR. RATHKE: Thank you, Your Honor.
REDIRECT EXAMINATION
BY MR. RATHKE:
Q. I'll be brief again. During cross-examination Miss Ghezzi took you through the locations where ////////// was found and asked you to identify where those areas were in the plant. Do you recall that?
A. Yes.
Q. Were all those areas within the red high hygiene area?
A. Yes, they were.
Q. Miss Ghezzi displayed to you Exhibit 1019 which was the 2008 CODEX document relating to EB as an indicator. Do you recall that?
A. Yes.
Q. Has there been any subsequent analysis or study with respect to the advantages or disadvantages of using EB as an indicator?

A. Matthias Fischer has done a lot of good work. And he's reported that a correlation between EB and E. sak has not been shown. And so the conclusion is if you want to find E. sak in a plant you should be looking for it directly.

Q. Is that the current scientific consensus?

A. Yes, it is.

Q. Is there anything about the cross-examination by Miss Ghezzi or any of the documents that she directed you to which change any of your opinions or conclusions that you gave earlier this morning?

A. No.

MR. RATHKE: Thank you. No further . . .

THE COURT: Well, Mr. Rathke, you know, brief is in the eye of the beholder. If it was putting a pin back into a hand grenade, wasn't so brief. But for a lawyer, I agree. It was brief.

Any recross?

MS. GHEZZI: No, Your Honor.

THE COURT: Okay. You may step down.

MR. GRAY: Your Honor, jury questions?

MR. KING: Jury questions.

THE COURT: Okay. Yep. Thank you. I knew you were sitting there for some reason, and now you've proved yourself extremely valuable. So thank you, Mr. King.

You know, I'm just going to read this one. You can

object if you don't like it.

What is the difference between presumptive positive and positive?

THE WITNESS: So presumptive positive, ////////////// //, ////////////////////////// you run a test. That /// test says it's positive. You need to go and then conf -- you can culturally -- well, you can do two things. If you want to be cautious, you could just go with the /// results, stop production, and start cleaning up, and that provides a margin of safety. You can also go and culturally confirm that positive result.

The easiest way to do it, take that ////////////, //////, the same one that gave you the positive result ////////// ////, streak it out to chromogenic media, and look for E. sak. That can be done within 12 to 24 hours. It's very simple.

// // // // // // ////////////

// //

//////////.

THE COURT: Okay. And follow-up questions? First Mr. Rathke?

MR. RATHKE: No, Your Honor.

THE COURT: Miss Ghezzi?

MS. GHEZZI: No, Your Honor.

THE COURT: Okay. Thank you.

THE WITNESS: Thank you.

THE COURT: Now, doctor, you may down. Mr. King, is it okay now?

MR. KING: Yes, Your Honor.

THE COURT: Okay. I'm relying on you. Thank you. Do I get a gold star for that? Okay. No, I do appreciate the heads-up.

MR. KING: Your Honor, plaintiff's next witness is Dr. Gerald Goldhaber. He's going to want to use his easel, so I need to do just a little bit of arranging.

THE COURT: Okay. Why don't you put your stuff down on the witness box, and then I can swear you in. Would you raise your right hand, please.

GERALD GOLDHABER, PLAINTIFF'S WITNESS, SWORN

THE COURT: Okay. Thank you. Please be seated. Make yourself comfortable. You can find that if you adjust the chair close enough to the microphones you'll be able to speak into them so that we can all hear you. And would you please tell us

your name and spell your last name.

THE WITNESS: I'm Dr. Gerald Goldhaber, G-o-l-d-h-a-b-e-r.

THE COURT: Your parents must have had incredible foresight by putting the name "Doctor" on your birth certificate.

THE WITNESS: Thank you. Gerald. G-e-r --

THE COURT: Right. There's a difference between your title and your name, isn't there?

THE WITNESS: Yes, sir.

THE COURT: Okay. I guarantee one thing, the questions are going to get harder.

THE WITNESS: G-e-r-a-l-d.

THE COURT: Thank you.

MR. KING: May I proceed, Your Honor?

THE COURT: You may.

DIRECT EXAMINATION

BY MR. KING:

Q. Dr. Goldhaber, what is your expertise, please?

A. I'm an expert in communication, organizational communication, safety communication, and warnings specifically.

Q. Tell the jury briefly your education.

A. I received a bachelor's degree in 1965 from the University of Massachusetts in the field of speech communication, minored in political science. My master's is in University of Maryland,

1967, in the area of communication theory, statistics, and measurement. And then I received my Ph.D. degree from Purdue University in Lafayette, Indiana, in 1970 in the area of organizational communication, industrial psychology human factors, and statistics and measurement.

Q. Doctor, what is your current employment?

A. I am president and CEO of Goldhaber Research Associates, LLC.

Q. Have you had earlier employment in the academic setting?

A. Yes.

Q. Tell the jury about that, please.

A. I was an assistant professor at the University of New Mexico in Albuquerque, New Mexico, from 1970 to 1974, and then I was an associate professor and deputy chairman and later chairman of the department of communication at the State University of New York in Buffalo from 1974 to 2004.

Q. And did your teaching at the college setting relate to warnings and instructions on consumer products?

A. Yes. I taught a undergraduate class in which about 20 to 25 percent of the material to 500 students every fall was in the area of safety communications and warnings. And then every other year I taught a Ph.D. seminar to doctoral students in communication and law school students on safety communications and warnings.

Q. Have you done writings within your profession on topics of

warnings and instructions?
A. Yes, I've published approximately two to three dozen scientific articles in the area of safety communication and warnings.
Q. Have you published any books on the topic?
A. Yes, I have. I've edited or published ten books in the field of communication, and some of my books referred to safety communication and warnings.
Q. Are you a member of any professional organizations that relate to consumer product safety warnings and instructions?
A. Yes.
Q. Tell the jury about that, please.
A. I'm a member of the Human Factors and Ergonomic Society. I teach every so often their course on warnings and safety communication. I'm former vice president and member of the International Communication Association. I'm a member of the National Communication Association and the Marketing Research Association.
Q. Doctor, what do you do in your current employment with Goldhaber Research Associates? What is that business, please?
A. We actually have three businesses. I oversee the company. The first business is a market and opinion research company. We do polls, focus groups, computer online surveys, mall intercept interviews, kitchen taste tests, an awful lot of the stuff that the Gallup Poll which I guess originated here in Iowa has done.

And then our second business is where we design, evaluate, and test warning labels.

And our third business is where I operate as an expert witness and have a support staff of two or three research librarians and my assistant who help me do the research that I use in my expert testimony.

Q. So the third business is the litigation-related business.

A. Yes.

Q. In the second business where you analyze the need for, design, and test warning labels for consumer products, have you done that work hired directly by industry?

A. Yes.

Q. Give the jury a few examples of different companies and different products and different safety issues that you've worked on.

A. I designed the -- I designed and tested and evaluated and placed the warnings for toxic shock syndrome on Playtex tampons.

I designed, tested, and placed the warnings on Cadbury beverages products which include 7-Up, Dr. Pepper, Orange Crush, Canada Dry, A and W Root Beer dealing with the cap that could explode and blow off and injure people's eyes.

I've designed and placed warnings on Owens-Corning Fiberglas Big Pink insulation warning the installers of insulation about possible lung disease. Those are just a few.

Q. Doctor, we've retained you in this case, have we not?

A. Yes.
Q. And we've asked you to advise us and evaluate the adequacy of the warnings and instructions that are related to the NeoSure product, have we not?
A. Yes.
Q. And we've provided you with a whole raft of materials relating to this case that you've reviewed?
A. Yes.
Q. Have you reached any opinions to a reasonable degree of certainty within your profession as to the adequacy of the warnings and safety instructions for the NeoSure product?
A. Yes.
Q. What is your opinion basically? And then we'll go through it in great detail.
A. Well, my overall opinion is that there is a hazard and it has sufficient risk relating to E. sak and consequences of meningitis, stroke, and possible infant death and that that hazard exists and was not warned about in any way by Abbott in its product NeoSure and that I believe a warning should have been on that product. And I believe that had a warning been on that product, it is more likely than not that Mrs. Surber would have paid attention to it and at least have had an informed choice whether or not to purchase that product.
Q. What is the basic process you employ as an expert whether you're working for an industry client or in a litigation matter

to make the kind of analysis you've just described?
A. Well, first of all, I want to know if there is a hazard. And I rely -- typically as a warnings expert, most of us rely on the scientific literature, or we rely on what other experts far more expert in this area of whether hazards exist or not than we are. And in this case, for example, I read the WHO reports, the World Health Organization reports, that identified the E. sak hazard.

Once I'm aware of the hazard and whether it exists or not, I want to know what the risk or the likelihood of occurrence of that hazard is. In the field of warnings, we've put warnings on products with risks ranging from very low statistics all the way up to the hundreds of millions-to-one statistic. In this case I looked at the available data on risk which range from the World Health Organization, one in a hundred thousand, all the way up to -- I suppose at the low end it could be a million to one based on four to six episodes a year in four million birth rates a year.

After I determine the risk, I look to see if there are any government standards or regulations mandating a warning. And in this case there were no government regulations or standards. The agency I believe would be the FDA, and there is nothing from the FDA mandating a warning.

And then I would look to see if there were competitors who were warning, and I didn't see any. And then ultimately I

would decide as a warnings expert whether I felt the risk and hazard was sufficient to recommend a warning.

Q. Do you try to determine whether or not the average consumer would be aware of the risk absent a warning?

A. That's a big part of it because in the field of warnings we use a phrase in my trade called the hidden hazard. Is it hidden from the average consumer? Is the average consumer at the time of purchase or use likely to be aware of the existence of this hazard? And in this case it was my opinion that there was a hidden hazard that the consumers were not aware and not likely to be aware of, the E. sak link to meningitis and possible death.

Q. In just broad terms, what is a warning within your field of expertise?

A. Well, like any communication, a warning is a message. It's a form of communication, a message intended to communicate that a dangerous situation may exist and that it's likely or possible to exist, what the consequences of exposure to that danger might be, and then what you can do or not do to avoid getting hurt or possibly worse than hurt, killed, by exposure to that hazard. That's what a warning is. It's a safety communication intended to tell people where they can get hurt and what they can do to avoid getting hurt or killed.

Q. And is there a maxim or axiom underlying the view of an expert in your field as to the need for warnings?

A. Yes. The bottom line in my field is give the consumer informed choice. If it's an open and obvious hazard like a knife, we all know knives are sharp. We don't need a warning on a knife. We don't need a warning on a pencil that tells you if you keep using it your hand's going to get tired and some people believe you might run the risk of carpel tunnel syndrome. We don't need to be told the obvious.

But in this case it isn't obvious, and the bottom line is warnings experts want informed choice among consumers. We want you to make a choice based on all the available information.

Q. Sir, in this case I think I heard you testify that you understand the risk associated with this product to be E. sak meningitis; is that correct?

A. Yes, the danger, the hazard.

Q. And is that a risk that you believe is open and obvious to the average consumer?

A. No.

Q. Why?

A. Well, the available data show that it isn't. For example, testimony from a representative of industry, Daniel March, who is an executive with Mead Johnson who also make a competitive infant formula product, has testifi -- has submitted a paper to the World Health Organization in which he stated that most caregivers and parents are not aware that infant formula is not

a sterile product.

A baby -- a breast-feeding organization, International Breast-Feeding Association Network I believe, IBFAN, has concluded the same thing, that caregivers and parents aren't aware.

There's a recent CDC survey from 2008 that says the same thing. It said that 70 percent of mothers or between two-thirds and 70 percent of parents of newborns believed that the infant formula did not have germs in it. In other words, they incorrectly believed that it was sterile or that it could not have germs. The survey didn't measure sterility, but they asked if they were aware it could contain germs, and they said no. And that's, of course, incorrect.

So the available evidence from the FDA even -- there was an employee in the FDA -- I believe his name was Benson Silverman -- he had testified or stated towards -- in some of the documents I had reviewed that the public, the parents and M.D.s and pediatricians, were not aware that powdered infant formula was not sterile. So the available evidence that was open to me was that it was a hidden hazard.

Q. Sir, in summary form, what specific information do you think that the NeoSure product label should convey to a consumer? And we'll go through it in some detail here in a minute, but just tick it off for me.

A. I think that it should tell the consumer that it isn't

sterile, and it should say so in a way that catches you your attention. I'll show you it's not communicated in a way that's intended to get your intention when I go over the label in detail.

Second -- so that's the hazard, that it isn't sterile. It should signal that hazard in a way that gets your attention. We call that in my field using a signal word. A signal word, you know what they are: Danger, warning, caution, attention. These are the words we see on warning labels.

I believe because this is an immediate life-threatening and serious hazard that the correct signal word should certainly be at least danger, and we should use the right colors to get your attention which you're all familiar with danger signs have the red and the white and the black.

Secondly, it should also -- thirdly, besides the signal word and a statement of the hazard, it should also state so what. Well, it isn't sterile. Does that mean I can get a cold, a flu, my infant could get sick, how sick? It should state specifically what the consequences of exposure to the hazard are. In this case it should mention at the very least meningitis, stroke, or death.

And finally, a warning, any warning, should tell the consumer what they need to do or not do to avoid exposure. In this case the warning should say -- offer the consumer, the parent, an option other than powdered formula that is sterile,

that is safe. And in this case I recommend the ready-to-feed which Abbott and others make themselves.

Q. Okay. Exhibit 2013, I think Pat has the label.

MR. KING: Would you put that up, please.

Q. Do you recognize this to be the label on the product that was fed to this child?

A. Yes.

Q. And have you created some audio/visual aids for us to describe exactly how you would change this label to make it appropriately safe?

A. Yes.

MR. KING: Your Honor, may I ask if the witness can stand and work with his demonstrative aids as he needs to?

THE COURT: That would be fine. Thank you.

MR. KING: You can take that down, Pat.

BY MR. KING:

Q. Okay. Dr. Goldhaber, we have a portion of the panel up. I guess it's not the middle of the panel, but that's a portion of the label we can see of the product in question in this case. What, if anything, would you change to that portion of the label to make it as safe as you think it should be?

THE WITNESS: How is that?

THE COURT: Much better. Thank you. And thank you, Matthew.

A. Well, first of all, I'd like to change this 0 to 12 months

and put 1 to 12 months.
Q. And why is that?
A. Because I believe according to the World Health Organization and other reports that I've read that the risk of E. sak is to not just prematurely born infants and low-birth-weight infants and infants whose bodies are immunologically compromised, but I believe the World Health Organization and others have stated that it's all neonates, to all children under 28 -- all infants under 28 days. So when you have 0 to 12, that goes below 28 days. So I would change that to at least 1 to 12 months.
Q. All right. What would you do next?
A. Just to reenforce that statement, I'd like to place the statement here that says not for infants under 28 days old. In case you missed the 1 to 12, let's be very clear: Not for infants under 28 days old. That's what the World Health Organization said.
Thirdly, as inviting and safe picture as this teddy bear is, I'm afraid I'm going to have to get rid of teddy to make room for what I believe is more important than the teddy bear which is just advertising. So if you'll forgive me, teddy, you're about to be replaced by a warning label right on the front.
Q. Read that to the jury, please.
A. And this warning states as I said earlier. It has all the

components of an appropriate warning approved by the American National Standards Institute: Danger, the appropriate signal word in red surrounded by a black border with white print, a triangle that's a triangle we use in my trade to -- again, it's a technique to get your attention. So we put a black exclamation point inside a triangle before the word danger. Danger, again meaning it's immediate and life threatening.

Second, the statement of the hazard: Infant formula is not sterile. Why? It may contain -- this is the consequence. Now remember I said hazard, consequence, and then the instruction. Here's the consequence. May contain dangerous bacteria that may cause meningitis, brain injury, or death to infants under 28 days old.

And finally, I think we need to tell the consumer, okay, well, what do I do now? What's a safe option? How about for infants under 28 days use Abbott's sterile liquid NeoSure ready-to-feed? I'm even referring them to Abbott, so go to Abbott's sterile liquid NeoSure ready-to-feed, certainly a safer option than the powdered infant formula for infants under 28 days old.

I have another couple things here I would recommend.

Q. Does that do it for that board?

A. For this board, yes.

Q. Okay. We'll set this down then.

A. Okay.

Q. Would you change any other part of the label?
A. Yes.
Q. Tell the jury about that, please.
A. You see over here on the regular label in the middle -- and this is blown up. But if you had the can -- I have a sample can with me -- it's in small print, and there's a bunch of words. And remember the statement of the hazard that I put on mine was pretty big. Right in the middle of this paragraph in the same size print as you see here, it says powdered infant formulas are not sterile.

Well, I'd like to make that at the very least bold-print capital letters. That's an important statement. That's the most important statement on the existing label as far as the hazard we're talking about. So at least make it boldfaced and capital. That's not an unreasonable suggestion.

And then finally, up here you've got the word caution. In my field, caution -- remember I was talking to you about signal words. Caution is the lowest of the three signal words. We have caution for minor bruises, scratches, cuts. That's what we say caution. It's not life threatening. It's not that serious.

Then we go up to warning. Warning is life threatening and serious like cigarette smoking, but it's long term. Maybe 20, 30 years down the road I might get sick.

Danger, that's more immediate. That's more immediate.

So why don't we say your baby's health depends on carefully following, let's make that danger. If we're serious about warning, then let's warn the right way. Let's tell the American consumer, the parent, the mother or the father, this is the risk, this is the hazard, this is the consequence, and here's what we need to do to avoid exposure to it.

Q. Are there any other portions of the label you would modify, sir?

A. That's the warnings I believe I would do.

Q. Okay. Take your seat then, please. There might be evidence or argument in the case, Dr. Goldhaber, that the risk of infection to a child from E. sak is minuscule, is tiny. Would that in any way affect your thinking?

A. No.

Q. Why?

A. As I said earlier, we've got warnings all over the place in the United States for risks that could be considered minuscule, tiny. Some of the warnings, for example, that I personally have designed for my personal clients in business and industry, I mentioned to you Owens-Corning Fiberglas who make Big Pink insulation. The actual risk as I calculated is -- to the 51,000 workers who daily install insulation for a living is one in a million that they will get some serious lung disease, one in a million. At the high end that's the risk that I've been told by industry they believe to be the risk associated at the high end

with powdered formula.

I mentioned Cadbury beverages. Cadbury beverages, the makers of 7-Up, Dr. Pepper, and a number of other soft drinks, for their 2-liter bottles before they changed the design on it, the risk of you getting hit in the eye, seriously injured to the point where you could go blind or maybe have serious harm to your eye, the risk was a quarter of a billion, a quarter of a billion -- that's 220 million to 1 -- of getting hit. And we put the warning on because the president of Cadbury told me they wanted to do the right thing, put the warning on.

Champagne -- we're right around New Year's -- many of us had some champagne to bring in the new year. Now, champagne you know is a French word only. We can't call the U.S. product champagne, so I'm only talking about French champagne. We import 17 million bottles a year from France to the United States. The risk of you -- and there's a government warning mandated by the U.S. government on all imported champagne bottles dealing with the bottle cap instructing people to not aim it at themselves or another person because it could blow off and injure them. The odds of that happening are one in three million to one annually, three million to one.

I just finished calculating the risk of raw milk. Raw milk in -- in fact, South Dakota just changed its warning last year on raw milk and, again, advising consumers that raw milk is dangerous, it can contain some deadly bacteria and give some

specifics in the warning about what can happen to you. The risk there approaches ten million to one, ten million to one of you being exposed to a raw milk serious hazardous condition.

I could go on, I mean. The risks are all over the place, and there are a number of examples out there of minuscule risks where we in industry, we who recommend to industry in the warnings field, put warnings on products.

Q. Let me ask you a question. If, in fact, the risk of E. sak meningitis to a child is only one in a million, why do you still believe a warning would be necessary?

A. I believe that the severity of this hazard is certainly important enough to pay attention to, and I believe that when you're talking about meningitis with infants who are full term, possibly full term, under 28 days of age neonates who may be exposed, may be exposed to meningitis that could cause brain injury as is in this case, that's serious. And I believe as a warnings expert and as a parent we owe it to parents to give them the opportunity for informed choice.

Severity, even though the risk is low -- I've never said it's a high risk. I've said it's a low risk. You can call it anything you want. Call it minor, minuscule, very rare, very low. But I've given you many examples in the United States where we have warnings for risks that are even much lower. And I as a parent and I as a warnings expert will be derelict in not recommending that warning because the severity of the harm

trumps the risk no matter how minuscule it is. You deserve an informed choice.

Q. Sir, sometimes we hear that there's too many warnings. Everything's got a warning on it. Do you have any concern about information overload with the warnings you're proposing here?

A. I have a concern about information overload all the time. I've been on national television a few times talking about that very thing. Supreme Court justices have said if you warn about everything you warn about nothing. I've written about the problem of information overload. I'm even one of the people that conceived that concept in one of my earlier books. I'm very concerned about information overload.

This is not an example of information overload. You only have one warning, Jerry Goldhaber's warning, on this product. The warning about microwave I have a little bit of an issue with in terms of whether that's even a full warning. But this is the only warning. And it's based on science. It's based on fact. And while the risk may be very low, the severity is very high. No, I'm not concerned about overload here. I'm concerned about parents having an informed choice.

Q. Sir, there's also I think a concept in your world called fear appeals and the inadequacy of warning on fear appeals. Explain that, please, to the jury.

A. What we mean by fear appeals is that if you -- we try to scare you into doing something that you may not have thought

about doing or you may think back to the early days of the seat belt warnings before they used to put them on television. They would actually show bodies being pushed against telephone poles. They were pretty gruesome. That's an example of over the top.

My warning is not over the top. I mentioned earlier raw milk requires warnings on it. And they in their warnings, they -- I'll read it to you. They talk about specific consequences including bloody diarrhea, vomiting, fever, dehydration, hemolytic uremic syndrome, Guillain-Barré syndrome, reactive arthritis, irritable bowel syndrome, miscarriage, or death. This goes on and on. And then they list all of the specific bacteria. I don't even mention E. sak on here. I just say dangerous bacteria. They -- the raw -- the raw milk warning --

THE WITNESS: Am I being warned?

THE COURT: No. Don't know what it is.

MR. KING: Is a battery dying on something?

THE CLERK: No, it's something calling in. The ringer's not on.

THE COURT: Another technology glitch.

A. Well, the raw milk warnings even state very specifically E. coli, campylobacter, listeria, salmonella, and so on. This is an example perhaps of one that might be fear appeals or over the top. It's very detailed and very specific.

This warning is not. This is a very -- I call it a

very neutral warning, dangerous bacteria that could lead to, and we spell out the consequence.

Q. Let me ask you about I think your final opinion. You've covered your opinions about warnings. And you've told us you have an opinion as to whether or not Mrs. Surber likely would have heeded a warning. Would you tell us why you are of that opinion.

A. Well, first of all, Mrs. Surber --

MR. REIDY: Your Honor, I would object just to the witness testifying about one specific human being doing something.

THE WITNESS: I was going to say she's --

THE COURT: Well, just hold on.

MR. KING: I can make an offer of proof if you'd like, Your Honor, to assist you.

THE COURT: Just hold off. You have to lay a foundation for it. It's not an offer of proof situation until I sustain the objection, and I may not.

MR. KING: I'm sorry, Your Honor.

THE COURT: So you can try and lay a foundation.

MR. KING: No, I'm waiting for your ruling. You need me to lay foundation, I'm happy to do so.

THE COURT: Yeah, the objection's overruled. It's premature.

BY MR. KING:

Q. All right. Let me ask it to you this way, Dr. Goldhaber. In your field is there a study of human behavior and consumer behavior as it relates to warnings?
A. Yes, there are several studies.
Q. And based upon that body of scientific and human factors and warning data, do you have an opinion as to whether Mrs. Surber is in a category of persons that would make it likely for her to heed this warning?
A. Yes.
Q. What is your opinion?
A. As I was saying, Mrs. Surber --
THE COURT: Aren't you going to object now?
MR. REIDY: Yes, Your Honor, I am. Apologize. Objection.
THE COURT: So the foundation is a study.
MR. KING: The foundation, Your Honor, is a study and research in the field of Dr. Goldhaber's --
THE COURT: Yeah, has he ever interviewed the plaintiff?
MR. KING: No, I'm not asking what the plaintiff would do. I'm asking if she's in a category of persons where we might predict what that category would do. As I believe he'll tell us, an established --
THE COURT: Just a second. Now it's a speaking objection. That isn't what you asked, category of people. You

asked about her specifically.

MR. KING: I'll rephrase.

THE COURT: That objection's sustained.

MR. KING: I'll rephrase my question.

BY MR. KING:

Q. Dr. Goldhaber, what do you know about Mrs. Surber?

A. Well, I know that Mrs. Surber testified that for the most part she followed the instructions on the package. I know that Mrs. Surber is not familiar with the NeoSure product because it's the first time she's used the product. I know that Mrs. Surber is a mother of an infant and is an -- what we call in my field in the category of an information seeker, someone seeking information. I know that Mrs. Surber is in a category or a group that the research has shown people with low familiarity with a product -- and this is a conclusion of studies I've done and that others have done -- that people with low familiarity with a product are more likely to pay attention to a warning.

And so with Mrs. Surber being an individual who is in all likelihood not familiar with this product, she's in a category or a group with low familiarity that would be more likely to pay attention to a warning.

MR. KING: That's all I have, Your Honor.

THE COURT: Thank you, Mr. King.

Mr. Reidy, are you cross-examining?

MR. REIDY: I am, Your Honor.

THE COURT: Thank you.

CROSS-EXAMINATION

BY MR. REIDY:

Q. Dr. Goldhaber, my name is Dan Reidy. We've not met; is that right?

A. Yes, sir. I mean no, we haven't.

Q. So you're an expert in the science of warnings; correct?

A. Yes.

Q. And you don't have any medical expertise.

A. No.

Q. And you're not an expert with respect to nutrition.

A. No.

Q. And you're not an expert in infectious disease or anything like that.

A. No.

Q. And you're not experienced with powdered infant formula issues; right?

A. No.

Q. And you've not worked in the industry with powdered infant formula; right?

A. No.

Q. And you've not interviewed or talked to the FDA about powdered infant formula.

A. No.

Q. Nor with the Center for Disease Control about powdered infant formula.
A. I haven't talked to them. I read their websites, both of them.
Q. But you haven't talked to anybody there. You haven't testified or been called in --
A. No.
Q. -- to consult with them.
A. No.
Q. And you're not an expert with respect to the regulatory scheme surrounding infant formula, are you?
A. No.
Q. And you're not an expert with respect to the regulatory scheme surrounding infant formula labeling, are you?
A. No.
Q. And you didn't know anything about E. sakazakii until you were hired in this case; right?
A. Hired in the earlier cases.
Q. Right. In a powdered infant formula case.
A. In powdered infant formula cases, correct.
Q. And your experience in warnings in the food industry is -- includes the Cadbury work you've described a couple times; right?
A. Yes.
Q. And have you written warnings for other foods?

A. I don't believe so, no.
Q. And so your warnings have been in areas other than food generally.
A. Yes.
Q. And to the extent you've dealt with food, it's been soft drinks?
A. Yes.
Q. And other than considering Abbott's ready-to-feed infant formula, did you consider any other alternatives in making your analysis?
A. Well, I read what others have said about the possibility of going to unsafe options which is why I put the safe option on the warning label.
Q. With respect to the warnings that you suggest, they make assumptions that the powdered infant formula -- that on some incidents powdered infant formula contains E. sak which infects children; is that right?
A. Yes.
Q. And if the powdered infant formula that is labeled like that does not contain any E. sak, then the label doesn't do anybody any good; right?
A. You mean if none of the powdered formula has E. sak? I'm talking in general now, not this particular batch. I'm not an expert in this batch. I'm talking in general.
Q. No, and that's fair enough. But the warning is meant to

take care of those circumstances where there is or might be E. sak in the powdered infant formula; right?

A. In general, yes.

Q. And if the steps that are being taken to keep E. sak out of the powdered infant formula at Abbott laboratories are sufficient to keep it out, then this warning would not be necessary; right?

A. I can't comment on those steps. That's not my field.

Q. Yeah, I'm not asking you to comment on the steps. I'm asking you a much more simple question. Let me see if I can restate it. If Abbott is successful in keeping E. sak out of its formula, then your warnings would not be necessary; correct?

A. That's right. If there is no hazard, there is no need for a warning.

Q. Now, the FDA has -- well, I should strike that.

You know that the FDA has the power to regulate what appears on that label; right?

A. Of course. They can tell you what to do, but they also don't prevent you from doing something.

Q. I'm sorry. I just asked you if the FDA controls and can mandate what's on that label; right?

A. Well, I was trying to answer you.

Q. Okay. I'm sorry. I should let you finish.

A. Yeah, I was trying to say the FDA can say you have to do this like they did in Playtex, or they can say nothing which is

what they've said here and they've left it up to you guys, your companies.
Q. Well, there are some requirements with respect to FDA.
A. Oh, sure. They've required you to put the nutritional information up there, the statements.
Q. And you testified I think that you examined the requirements and that the label meets the FDA requirements.
A. Absolutely.
Q. And the label actually includes some things that aren't required by the FDA; right?
A. That's right, including the statement on sterility.
Q. So the FDA doesn't require that the label say that the product is not sterile, but the label does not say that the product is not sterile.
A. That's correct.
Q. And the warning that you've decided was most appropriate -- and let me just put it up again. That's not the warning. Almost lost my warning. So that one says that infant formula is not sterile after the danger sign; right?
A. Yes.
Q. And it talks about may contain dangerous meningitis, brain, injury or death -- can cause meningitis, brain injury, or death to infants under 28 years -- days old; right?
A. Yes.
Q. And then it basically directs people not to use this

product for infants under 28 days old; right?
A. That's correct. It directs you to use NeoSure's ready-to-feed.
Q. So your warning label makes the public policy decision that no baby under 28 days of old -- age should be using powdered infant formula.
A. I'm not making any public policy statement. I'm making a statement that this is a safe option and that you should consider it. I'm giving parents an informed choice.
Q. But you're not saying -- your warning doesn't say think about it, make up your own mind. It says if your baby is under 28 days of old -- age, don't use this product; use another one.
A. That's exactly right. But some mothers -- I'm giving them choice. A mother may look at that -- and our warnings literature, as you know I'm sure, predicts that most people ignore warnings. I admit to that. And, therefore, we're giving them choice. Let them choose.
Q. But they have to choose, as you would put the label, to disregard your label.
A. People do that all the time. I'm not that proud of -- I mean, I love my labels, and I believe in them, but I'm not an idiot. People ignore warnings. I'm giving them a choice. That's all I said.
Q. And your choice makes the public policy decision that powdered infant formula should not be used for babies under 28

days of age.
A. I'm not a regulatory agency, sir. I'm not making that policy decision. I'm suggesting in my label that this is the way to go; you choose.
Q. But if that label -- if the label you suggest is put on, it tells the consumer they shouldn't use this product if their --
A. If they --
Q. Let me finish my question. If their child is under 28 days of age.
A. Yes.
Q. And so that is a major public health decision, is it not?
A. It is a major public health decision, and I am recommending to parents that they take that warning seriously.
Q. And that's based on what you've read about what you think the dangers are of powdered infant formula.
A. Yes.
Q. And it's not based on what the FDA thinks the dangers are for powdered infant formula.
A. I think the FDA's well aware of what the dangers are.
Q. Have you seen the FDA's responsive letter to Dr. Jeanine Jason?
A. I don't believe so.
Q. Let me take a minute and show it to you, and I'm going to direct your attention to page 2. There's a sentence there. But you can take a look at whatever you need.

MR. REIDY: Is that all right, Your Honor?
THE COURT: Yes.
MR. REIDY: Thank you.
MR. KING: Could I have the exhibit number, please?
MR. REIDY: It's Exhibit 1041.
MR. KING: Thank you.
BY MR. REIDY:
Q. Do you see the sentence that I've marked there?
MR. KING: I'm sorry. What page?
MR. REIDY: Page 2.
MR. KING: Thank you.
Q. Maybe I can read it for you. It says it is unknown how the infant formula becomes contaminated with C. sakazakii, but the evidence from investigations thus far is consistent with packaged powdered infant formula being negative for C. sakazakii when it leaves the manufacturing plant. Do you see that?
A. Yes.
Q. If it is true that with respect to the infections of infants from powdered infant formula that there is -- that the evidence is consistent with the powdered infant formula not containing the bacteria you're warning for, then your warning shouldn't appear there; right?
A. If all infant formula were such, then there would be no hazard and thus no need for my warning.
Q. Well, we're only talking about the warning you want on

Abbott's NeoSure; right?
A. Oh, no. I would put this warning -- I'm in this case talking about Abbott and NeoSure, but I believe I would put this warning on all powdered infant formula.
Q. And if it's the case that it's the FDA's view that the evidence is consistent with the powdered infant formula available for neonates in this country being free from C. sakazakii when it leaves the plant, then your warning isn't appropriate, is it?
A. If there is no hazard, there is no need for warning.
Q. And so the answer to my question is yes.
A. Yes.
Q. Thank you.
MR. REIDY: That's all I have, Judge.
MR. KING: I have nothing further, Your Honor.
THE COURT: Okay. Members of the jury, do we have any questions for the doctor? Doesn't look like it. You're excused. Thank you.
And everybody can take a stretch break. And are you ready to call your next witness?
Well, rather than keep you waiting, we'll just take our --
MR. RATHKE: We're ready I think.
THE COURT: I've been waiting for you to call a witness.

MR. RATHKE: Oh, I'm sorry. I thought you -- okay. Your Honor, the next witness --

THE COURT: I said call your next witness.

MR. RATHKE: The next witness would be Dr. John Treves testifying by video deposition.

THE COURT: Okay. And how long will that be?

MR. RATHKE: Forty minutes.

THE COURT: Okay. Why don't we do 10 minutes of it or so or 15 minutes and then take a break. Thank you. Please be seated.

I was waiting for a witness to walk through the door. I'm not clairvoyant. I don't know who your next witness is.

(Video deposition of John Treves was played in open court.)

THE COURT: You can stop at any time. Well, you might want to have him answer the question and then start before the next question's asked.

(Continuation of video deposition.)

THE COURT: Thank you. Members of the jury, we'll have a 25-minute recess until 5 to 1. Please remember to keep an open mind till you've heard all of the evidence. Thank you.

(The jury exited the courtroom.)

THE COURT: You know, I know it's a novel concept apparently for you all to have a witness list with the witnesses in the order in which you are actually calling them. It's kind

of like playing Whac-A-Mole with your witness list. You never know who's going to pop up next. I've never had a witness list where the lawyers didn't basically follow it with the exception of somebody having transportation problems and this problem and that problem. But I never know who's going to pop up next.

MR. KING: Your Honor, Dr. Joyce is next on our list. He's on at 1:30, so we didn't want to waste time --

THE REPORTER: I can't hear you.

THE COURT: Yeah, I can't hear a word you're saying. We've gone over that.

MR. KING: I'm sorry.

THE COURT: I'm not interested in that. I'm interested in why we're jumping all over the place on your witness list, but that's fine. But it's not very helpful. Do you get that or not?

MR. KING: Yes, sir, yes.

THE COURT: That's a --

MR. KING: Yes. I understand that completely.

THE COURT: Okay.

(Recess at 12:30 p.m.)

THE COURT: Have the jury brought in.

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

You may continue with the deposition.

(Continuation of video deposition.)

THE COURT: Ready to call your next witness?

MR. KING: Yes.

THE COURT: Why doesn't everybody take a stretch break.

STEVEN JOYCE, PLAINTIFF'S WITNESS, SWORN

THE COURT: Thank you. Please be seated in the witness box there, and you can adjust the microphones and the chair so you can speak directly into them. And could you scoot up a little bit closer? And would you tell us your name, please, and spell your last name.

THE WITNESS: My name is Steven P. Joyce, J-o-y-c-e.

THE COURT: Thank you.

Mr. King.

DIRECT EXAMINATION

BY MR. KING:

Q. Dr. Joyce, what is your profession?

A. I'm a physician.

Q. And do you have a specialty?

A. I have dual specialties in internal medicine and pediatrics.

Q. And are you board certified in either of those or both of those areas?

A. I am board certified in both specialties.

Q. Where do you practice?

A. My office is at Mercy Medical Center here in Sioux City,

Iowa.
Q. Have you been a caregiver to Jeanine Kunkel?
A. I have.
Q. Do you recall when you first saw her?
A. I do.
Q. What's the date?
A. Back in June of 2011.
Q. Are you able to tell us from your memory what her admitting history was, or would it assist you to look at a copy of your note?
A. I recall as I reviewed my own notes prior to coming at least for that visit, she was coming in I believe for a respiratory infection at that time. And we saw her, reviewed her medical history in detail at that time with the mother, and I believe she had another caregiver nurse I believe with her at that time if I recall.
Q. Do you recall receiving any history about the history of her illness?
A. I -- we did discuss the history of her illness with her mother at that time as it was pertinent to her case.
Q. What's your understanding?
A. As the mother reported, that Jeanine, when she was an infant, had suffered meningitis which had led to many of the complications that we were going to have to deal with in her care going forward.

Q. Did you understand that she had a history of a seizure disorder?
A. I did.
Q. And of a gastrointestinal disorder?
A. She did. She had esophageal reflux which can oftentimes complicate these issues, and she was fed via G tube at that point.
Q. And did you form an assessment on that first visit?
A. We did. It's sometimes difficult in an acute visit like that to summarize a difficult case with many complications, but she was treated and -- examined and treated appropriately at that point and certainly needed much follow-up to continue to provide her care.
Q. She would have been I think just over four years of age when her -- is it three?
A. Yeah, I think --
Q. Three or four years of age when you first saw her. Does that seem right to you?
A. Yeah, it was June of '11, so correct.
Q. Can you describe to the jury in lay terms what her level of functioning was and what her issues were.
A. She -- at that point for her age, she was significantly delayed for her age. A typical three-year-old should be walking and talking and jumping, and approximately, you know, 50 to 75 percent of their language should be intelligible by strangers,

certainly understanding stranger anxieties and things like that and have normal interactions. Jeanine at that point, she probably had the intellectual function of probably a four-month-old. She really couldn't roll. She certainly couldn't sit, walk, or talk. She could smile and interact with her parents as many four-month-olds could do. But she was significantly delayed in all aspects of her milestones.

Q. You have continued to follow her to the present time?

A. I have.

Q. And how would you characterize her functioning at this time?

A. She's -- she's maybe progressed a little bit in regards to her functions. In pediatrics we look at milestones in social, language, gross motor, and fine motor. And in Jeanine's case, she is grossly delayed in all of those functions and continues to be so. She makes perhaps a little bit of progress each year in some of them, but she's unable to speak intelligibly. She certainly is not able to crawl or bear weight without significant assistance. She continues to need a lot of care.

Q. You are a pediatrician. Tell the jury what the expertise of a pediatrician is, please.

A. Pediatricians simply specialize in the care of children ages newborn to 18 years of age.

Q. And internal medicine, that's another specialty of yours?

A. Correct.

Q. And how does that compare to the specialty of a pediatrician?
A. Internal medicine, our slogan is simply doctors for adults. Not many people know what an internist is, but that's what we do. So we simply provide care for adults, and that would be from age 18 upwards. Some internists will see some children with diabetes and things like that at a younger age perhaps, but typically internists take care of patients 18 years and older.
Q. Doctor, I'm going to ask you if you have opinions. I want you to be sure to not express them if you don't hold them to a reasonable degree of medical certainty. Will you do that?
A. Yes.
Q. Do you have an opinion as to whether or not Jeanine has been left with a permanent injury or limitation as a consequence of her meningitis?
A. In my professional opinion and expertise, Jeanine has been left with a permanent disability, yes.
Q. And what would you predict for her future from a medical standpoint?
A. Jeanine will never be able to live alone, walk, probably not talk to any intelligible perception. She will continue to need care the rest of her life without question.
Q. When you first met the family -- maybe you told us this. If you did, I apologize. But when you first met the family, did they report to you their concern that her meningitis related to

the consumption of powdered infant formula?
A. I believe at that time the mother stated it almost more of a matter of fact than anything. She -- to my recollection at least in looking at my notes, the mother had said, you know, she -- her care as she prescribes now was due -- her case was due to meningitis from E. sak from her formula. That was just a matter-of-fact statement from the mother rather than my assumptions placed at that point.
Q. I understand. And when had you started your practice?
A. I came here to Sioux City in the year 2000.
Q. As of the time you first met Jeanine, did you have any knowledge or understanding as to whether or not powdered infant formula is sterile?
A. I did not. Really never gave it any thought.
Q. Did you know whether it was sterile?
A. I had presumed that powdered infant formulas would be sterile.
Q. Did you have any knowledge as to whether or not there might be a risk of E. sak infection to neonates or other immunocompromised babies from powdered infant formula?
A. No.
MR. KING: That's all I have. Thank you.
THE COURT: Thank you, Mr. King.
Mr. Gray?
MR. GRAY: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. GRAY:

Q. Good afternoon, Dr. Joyce. How are you today?

A. Good. Thanks.

Q. Thank you. Mr. King used the term E. sakazakii. Have you ever had a patient other than Jeanine Kunkel who has had an exposure to E. sak?

A. I have not.

Q. When you first saw Jeanine about June 27, 2001 -- or 2011, excuse me, that was when her mother and another caregiver brought her to your office; am I right?

A. Correct.

Q. And since that was the first time you'd seen this new patient, you didn't know much about her when she first came, did you?

A. That's correct. I can say that when I was -- my first eight years here in Sioux City were at another practice, and oftentimes you'll hear of other cases in the community, and so whenever there's a case of a bacterial meningitis such as this, sometimes word is scattered around. But that's -- it was only very peripheral knowledge of the case at all.

Q. And certainly as a new patient, you don't go and get her previous records to read those before she comes to see you, do you?

A. Obviously we had no opportunity to do so. We certainly

request those once the patient is there so we can review the chart afterwards, yes.
Q. And one thing you do when you have a new patient, you rely upon -- in this case when you have a child, you have to rely upon the mother to tell you some things.
A. Absolutely.
Q. That's called the history?
A. Correct.
Q. And as you do the history, am I correct that you write down what the mother tells you without cross-examining her?
A. That's correct.
Q. If she says that the child had a infection from infant formula, you don't know whether that's true or not true.
A. No. At that point without review of other records and expertise, you take that as the truth since it's reported by the parent, correct.
Q. And, frankly, three years after the fact, it wouldn't matter to you how she obtained that bacterial meningitis. You're going to treat the symptoms that are presented to you on that day.
A. That's correct.
Q. Do you recall when you first saw Jeanine and her mother that her mother told you that she had had a disagreement with her previous pediatrician about the amount of home healthcare he was authorizing? Do you remember that?

A. I do.
Q. Now, since that time, sir, have you become involved at all in the decisions as to how much home healthcare Jeanine should have?
A. Not at all. And I could say that that's just not my area of expertise. As a pediatrician, we treat the child. Most often we leave that to the healthcare providers who are in the home to allay (sic) to us how much healthcare they think that they need for that child.
Q. So in other words, that's just not your role.
A. Correct.
Q. Well, let me talk about something else that probably is in your records. When Jeanine was presented to you on June 27 of 2011, did she tell you -- did her mother tell you that she had had a history of seizures but had not had one for the previous six months?
A. That's correct.
Q. And did she tell you at some point during your care of her that she, her mother, had fallen on the ice and that she had hit Jeanine's head and after that there were a series of seizures?
A. Yes.
Q. Now, other than that one episode, have you documented any seizures that Jeanine has had since the time you became her pediatrician?
A. Not to the best of my knowledge.

Q. I assume that Jeanine has come to see you for things such as pneumonia, upper respiratory infections, stomach flu.
A. Yes.
Q. Are those conditions you would often see in children presented to you?
A. Quite commonly, yes.
Q. Doesn't have anything to do with whether or not she has meningitis. It's a typical childhood disease?
A. They are. If I may expound on that just a bit, children in her case who are -- are going to be at increased risk for more especially upper respiratory illness since they have a more difficult time handling their secretions and such, so although she has the typical childhood illnesses, she is certainly at more risk at developing especially respiratory illnesses and the like.
Q. And you have certainly seen her for some fairly serious conditions.
A. We have.
Q. And you continue to do that.
A. I do.
Q. Let me talk to you a little bit about powdered infant formula. As a pediatrician, do you sometimes make formula recommendations?
A. I do.
Q. And would I be fair to say that you have no concerns with

recommending powdered infant formula for infants?
A. That is fair to say.
Q. In fact, would it be fair to say that the majority of your parents use powdered infant formula?
A. I think at some degree those who are not exclusively breast-feeding would almost certainly be using powdered infant formula of some degree.
Q. And do you have an understanding of why your patients would prefer powdered infant formula?
A. If I read -- you know, from my discussions with patients, it's mostly a cost issue. Powdered infant formula's simply cheaper than most of the liquids prepared. Certainly breast-feeding is best, and that's what we as pediatricians continue to recommend universally. But in those who choose not to breast-feed or those who are unable to go to some brand of formula, and almost always at some point they eventually go to the powdered formula because it's less expensive.
Q. Are you familiar with the abbreviation WIC?
A. Yes.
Q. What is that, sir?
A. Women and Infants and Children.
Q. And is that a program where the government steps in and purchases formula for a small child?
A. Yes. It's a subsidized federal -- I believe it's a federal subsidized program where they are able to provide nutritional

supplements to those who are unable to afford it, and they will provide formula to infants and children, yes.
Q. And does WIC generally provide powdered infant formula?
A. I'm not sure that I can answer that question. I believe that they do.
Q. If -- from your experience if they want to use something other than powdered infant formula, do you have to write a prescription for that?
A. I do.
Q. Of course, this is not involving Jeanine Kunkel. She doesn't use formula anymore, and you've never recommended any to her; is that correct?
A. No. By the time that she came to me, she was on other nutritional supplements besides formula, correct.
Q. Let me talk to you a little bit about this concept of sterile. Liquid formula, ready-to-feed formula, that's not sterile, is it, once it's out of the bottle?
A. No. Once it's gone to the bottle, it would be considered nonsterile.
Q. So if it's put from the container it comes in and put into a baby bottle or hits the nipple, it's not sterile anymore, is it?
A. Correct.
Q. And is tap water sterile?
A. Tap water would not be considered sterile.

MR. GRAY: Dr. Joyce, thank you very much.

THE COURT: Any redirect, Mr. King?

MR. KING: Yes, Your Honor.

REDIRECT EXAMINATION

BY MR. KING:

Q. You just testified you have no concern, if I got it right, about powdered infant formula for children. Do you have any concern about powdered infant formula for neonates or low-birth-weight or premature children?

A. No.

Q. Does the -- if, in fact, there's a proven association between E. sak meningitis in powdered infant formula and low-birth-weight or premature or immunocompromised or neonates, would that change your thinking?

A. It would.

MR. KING: Thank you.

THE COURT: Mr. Gray, anything further for Dr. Joyce?

RECROSS-EXAMINATION

BY MR. GRAY:

Q. And, Dr. Joyce, if there is no connection between E. sak and low-birth-weight or premature babies, you would have -- is it fair to say you would have no concerns about powdered infant formula?

A. That would be correct as well.

MR. GRAY: Thank you.

THE COURT: Dr. Joyce, we're just going to wait and see if any of the jurors have any questions for you. Are there any questions for Dr. Joyce? Doesn't appear to be. Thank you. You're free to leave.

Mr. Rathke, what's next? Do we have depositions to read or live witnesses?

MR. RATHKE: We have a deposition to read by Summer Johnson, a therapist.

THE COURT: Okay. And who's going to be doing the reading?

MR. RATHKE: I will play the part of the attorney that took the deposition, Kate Westad. And Ms. Van Wyhe will play the part of the witness, Summer Johnson. And Patrick -- Mr. Persons will play the part of the defense attorney.

THE COURT: Okay. Why don't we actually have the person playing the part of the witness actually sit in the witness box.

And let me just kind of explain it to the jury. The next evidence you're going to hear is from a deposition. A deposition is a statement taken under oath prior to trial. Sometimes but not always the reason why the deposition is taken is because the person won't be available to testify in court. And so it's fairly common in trials to have depositions being read. And so it's -- you have to assume it's just like testimony given here in court which it is. But you don't have

the actual same people doing the reading. If we did that, we wouldn't need to read the deposition. We'd have the person here live.

So why don't you just go ahead and explain who's reading who now. Miss Van Wyhe is the deponent.

MR. RATHKE: I will be reading the words uttered by Attorney Kate Westad who is a law partner in my law firm --

THE COURT: Okay.

MR. RATHKE: -- and who took the deposition. Ms. Van Wyhe will be reading the part of the witness, Summer Rae, R-a-e, Johnson. And Mr. Persons will be playing the part of the Abbott attorney, Gabriel -- help me out.

MR. SCANNAPIECO: Scannapieco.

MR. RATHKE: -- Scannapieco who took the deposition on behalf of Abbott.

THE COURT: Okay. You may proceed. Thank you.

MR. RATHKE: Thank you, Your Honor.

(Deposition designations of Summer Johnson were read in open court.)

THE COURT: Just a second. I've overruled all those objections.

MR. PERSONS: I won't read them.

THE COURT: So why would you read them? Remember in the beginning of the instructions when I said objections by lawyers are not evidence?

(Continuation of deposition.)

MR. PERSONS: That concludes the deposition.

THE COURT: Thank you.

What's next?

MR. RATHKE: Your Honor, we have a deposition by Karl Olson, an employee of Abbott, who will not be testifying. It will take about ten minutes to read the designated part.

THE COURT: Okay. Thank you.

MR. RATHKE: And I will play myself. I took the deposition. Patrick Persons will be Dr. Karl Olson. And there is one question by Ms. Ghezzi, question that she asked, which was answered that we've designated. And when we get to that, Ms. Van Wyhe would play the part of Miss Ghezzi.

THE COURT: Okay. Thank you.

MR. RATHKE: You have to go up there, Patrick.

I'd note for the record that this deposition occurred on December 8, 2011, and I represented the plaintiff. Miss Ghezzi represented Abbott. All set?

(Deposition designations of Karl Olson were read in open court.)

MR. RATHKE: That's the end of the deposition.

THE COURT: Thank you.

Well, I think we're pretty close to the end of time, so we're -- do you have another short deposition in duration or . . .

MR. RATHKE: No, I was going to say the next deposition's about 30 minutes.

THE COURT: Okay. Well, I think we'll just take that up at 8:30 tomorrow morning.

Members of the jury, please remember to keep an open mind till you've heard all of the evidence. And let's see. I've lost track of -- what's tomorrow? Friday or Thursday? Friday? Whoa. Friday. So I'll give you an update tomorrow on where I think we are in terms of the progress or lack thereof of the case so you can plan your lives accordingly.

Don't read any newspaper stories, do any research, et cetera. Don't discuss the case with anybody else. And like I said just a second ago, keep an open mind till you've heard all of the evidence. And we'll see you tomorrow morning at 8:30. Thank you very much.

(The jury exited the courtroom.)

THE COURT: Please be seated. You know, it's a small thing, but I'm just curious about this reading the objection. You know, I've been at this 20 years. I've never had a lawyer do that. I assume virtually every judge instructs that objections, comments, arguments by the lawyers are not evidence. That's a stock instruction in every circuit that I'm aware of. It just struck me as odd. So for my own edification, what am I missing here?

MR. RATHKE: Your Honor, not in the depositions so

far, but, for example, there's one instance in Karl Olson's deposition that -- or maybe not in Karl Olson's but in some of the depositions, many of the depositions, Miss Ghezzi actually asks the question that was answered or rephrased the question so that the --

THE COURT: Yeah, I noticed a lot of that was going on. She didn't like the question or she had a better way to phrase it. She'd rephrase it. Then the witness would answer it. So if that's what's going on . . .

MR. RATHKE: We'd like to be able to read her part.

THE COURT: Why did you object to it then and have me rule on the objection if you wanted to be able to read it?

MR. RATHKE: I didn't object to it.

THE COURT: Pardon me?

MR. RATHKE: I didn't object to it. We nominated it. We designated it.

THE COURT: Well, if you objected to it, I sustained it.

MR. RATHKE: Your Honor, I didn't object to it. We designated that and asked the Court to be able to read it. She objected --

THE COURT: Well, of course, you can do that. But was that what was going on? That was a desig --

MR. RATHKE: We designated portions of the --

THE COURT: No, in what he just read earlier when this

came up and I said don't read the objection.

MR. RATHKE: That shouldn't have been read. I agree.

THE COURT: Okay. But where you designated, you can read it.

MR. RATHKE: Okay.

THE COURT: Right.

MR. RATHKE: We're good.

THE COURT: Okay. I see. That's where the confusion was. You had designated some things. This is helpful to me now. I'm understanding. You had designated some things that included the objection.

MR. RATHKE: Yes.

THE COURT: There was no cross objection wanting me to keep it out.

MR. RATHKE: Oh, no. I never --

THE COURT: And so, of course, you can read that. You bet.

MR. RATHKE: Thank you.

THE COURT: Okay. No, I appreciate the clarification. Anything else we need to take up?

MR. RATHKE: Yes, if the Court would. Exhibits 160 and 161 are judicial admissions, one made in the -- Abbott's answer and the other made in a statement that they affirmatively set forth. We would -- we have asked that those be admitted. The objection is hearsay, and our response to that objection is

that it's judicial admission by a party opponent.

THE COURT: What do you mean by judicial admission?

MR. RATHKE: Well, it was -- that's a term that I thought applies. It's where an admission is made in court.

THE COURT: Well . . .

MR. RATHKE: It's an admission by --

THE COURT: As far as I know, they weren't in the courtroom when they filled out their answer, so that's not exactly accurate either. An answer isn't made in court. An answer is filed. But the question you have is, I think, is a statement in an answer an admission which would be an exception to the hearsay rule.

MR. RATHKE: Yes, Your Honor.

THE COURT: I don't know the answer to it. I've allowed it before. Why wouldn't it be an admission? Mr. Gray, you're closest one to me. Why wouldn't it be an admission?

MR. GRAY: Your Honor, if I remember the Iowa rule correct -- can I stand over here?

THE COURT: You can sit or how ever you want to do it.

MR. GRAY: If I remember the Iowa rule correctly, there are certain things in a petition or an answer that are deemed admissions, particularly those that are admissions of fact. But as to what they call allegations of law, unless those -- those generally are not read to the jury or admitted to the jury, at least in state court. That's been my experience.

THE COURT: Okay. And let's take a look at 161.

MR. RATHKE: Your Honor, I'm going to withdraw -- I think we have that in evidence. I think I'm going to withdraw 161. But 162 is --

THE COURT: Which one's the answer?

MR. RATHKE: The answer --

THE COURT: It's 160; right?

MR. RATHKE: 160 is paragraph 41 of their answer. And, Your Honor, I'm particularly interested --

THE COURT: Let me just read it.

MR. RATHKE: Okay.

THE COURT: Okay. And what is it that you're jazzed up about that you want to get into evidence?

MR. RATHKE: The statement where Abbott says Abbott also admits that E. sak is not intrinsic to the product, is not a characteristic of the product, and is not part of the intended design of the product. And I think that's relevant to the manufacturing defect because if the jury determines that E. sak was in the product, then that would take us a ways down the road to show a manufacturing defect.

THE COURT: Well, like -- it's stating the uber obvious. I can't even imagine there's a fight over this but . . .

MR. RATHKE: Well, they objected to it.

MR. REIDY: May I, Your Honor?

THE COURT: Well, yes, Mr. Reidy. But before that, using the dichotomy that you discussed, Mr. Gray, which seems kind of a reasonable one just, you know, not knowing the answer to it, these seem like factual assertions to me.

MR. GRAY: Yes. If we're talking about the -- I'm sorry. Your Honor, they do seem like factual assertions to me on the last -- the one that Mr. Rathke just read starting with Abbott also admits.

THE COURT: Yeah.

MR. GRAY: Yeah.

THE COURT: I mean, okay. Let's see why the defense has an -- I mean, that's your whole theory of your case, that it isn't.

MR. REIDY: Judge, I think that the reason we object is because it gets a little messy when it starts out talking about 41. As far as the actual factual assertions in here, we don't have any problem with them, and I didn't get a chance to discuss this with Mr. Rathke. We can either work out a stip or something. The part I don't like is in order to really sort of flesh this out you have to include paragraph 41 of the complaint, and then it starts to be a bunch of legal mumbo jumbo being put in front of the jury.

THE COURT: Right.

MR. REIDY: So maybe Mr. Rathke and our side can work it out where it just becomes a stipulation because Your Honor's

quite correct. This is our position. It is a fact, and we don't have any real problem with this.

THE COURT: So here's my problem. I can't possibly see how it helps the plaintiff, and I can't possibly see why you would have an objection to it. But I do understand your other part of the objection about this other stuff which we'd be confusing because it's talking about the first sentence of paragraph 41. They don't even know what paragraph 41 is. It's the complaint. But the jurors wouldn't know that.

So in -- you suggested it. I'm gr -- I've never had a good idea in my life, but I copy others. So what about if you just work up -- add that last sentence, modi -- you know, Abbott also admits or Abbott admits and just add that to your stipulation?

MR. REIDY: I think we can work that out, Judge.

THE COURT: Yep.

MR. REIDY: I don't think we have to bother you further.

THE COURT: Okay. Great. Thanks. You know, I've always said great lawyers come up with good solutions.

MR. RATHKE: Your Honor, may I bring another --

THE COURT: They don't create problems. They solve them. Yes.

MR. RATHKE: Yes. Exhibit 141 is a document that we received from the Iowa Department of Health and represents the

subrogation interest. In August we presented this -- essentially this document. It's been updated since, and Abbott gave it an A, so we thought nothing more of it.

When we submitted the updated version in November to Abbott -- when we got their response shortly before the pretrial, they had rated it a B and made an objection to relevance asserting that some of it doesn't -- has nothing to do with her injuries. The document itself has been redacted by the Iowa Department of Health. It was sent to us at -- you know, knowing full well that we were involved in this lawsuit, and it was redacted by the department to eliminate any medical expenses that had been paid that were not related to her illness.

And I asked Abbott if you could tell me what entries that you think weren't related, you know, we'll take them out and got no response, and their objection still stands that the document is not relevant. They do not have any other objection other than relevance.

THE COURT: This is how you're proving the actual out-of-pocket medical expenses?

MR. RATHKE: Well, yes, because we don't -- because they had no objection to its foundation or hearsay, so that is how we intend --

THE COURT: Rather than actual having all the bills in one exhibit --

MR. RATHKE: Right.

THE COURT: -- with a summary of it.

MR. RATHKE: Yeah. And there's a total in there that gives the total, and that represents past medical expenses that have been paid. That's all we're asking for. We're not asking for their -- you know, some market value of them or anything like that. All we want is essentially the subrogation claim from Medicare -- Medicaid. So the objection is relevance, and our view --

THE COURT: That's where I'm getting confused. You want -- traditionally a plaintiff proves their medical expenses by having all of the medical bills usually in a single exhibit with a total or a summary. What -- so you're not doing that. You don't have to do it. I'm just saying that's how it's usually done. We're not doing it that way.

MR. RATHKE: No, we're not doing that. We're just submitting the bills that were paid or the amounts --

THE COURT: Isn't that what I just said?

MR. RATHKE: Yes.

THE COURT: Or did I say something different? Here's what I said. Traditionally plaintiffs prove medical expenses by submitting the bills -- they don't actually have to have been paid -- the bills that they received that are based on the injury they're claiming. Oftentimes they'll have those in one exhibit, and because they come from many different providers, there will be a summary of it. And then I asked you if that's

how you were doing it. You said no, you wanted to do it through Exhibit 141.

MR. RATHKE: Well, 141 is not the bills. 141 is simply a record of Medicaid payment. We don't have the bills.

THE COURT: Do you ever listen to what I say, or are you just so busy thinking about what you're going to say next that what I say goes in one ear and out the other like are you going to call your next witness and I'm standing there for 4 minutes waiting for you to call your next witness and you're going to show a videotape that I didn't know you were going to show a videotape because you don't listen to what I say?

MR. RATHKE: Maybe I misunderstand what you say, but these aren't the bills. It's the record of the payment.

THE COURT: Yeah, you're not understanding what I'm saying. This is the subrogation claim?

MR. RATHKE: Yes, Your Honor.

THE COURT: Well, are all her medical expenses subrogated, every single penny?

MR. RATHKE: Every single penny that's paid.

THE COURT: Who's handling this for the defense?

MR. REIDY: Judge, I am.

THE COURT: Okay.

MR. REIDY: Judge, I think the most efficient use of your time would be to tell us to go home and Mr. Rathke and I will have a conversation; we'll see if we can't work this out.

THE COURT: Awesome. I have every confidence that you'll be able to do that. Thank you.

MR. REIDY: Thank you, Judge. Have a good night.

THE COURT: Thank you.

MR. RATHKE: I don't want the Court to think that that hasn't been tried.

MR. REIDY: No, we're not saying that.

THE COURT: I'm not interested whether it's been tried or it hasn't been tried. I'm interested in the fact that the defense has made a good-faith offer to try and get it resolved. So it's going to be hard for me to fall asleep at night knowing that you are debating this, but I'll wait till tomorrow morning. I'll try and be patient, wait till tomorrow morning, find out what happens.

MR. REIDY: I suspect it won't keep you up, Judge.

MR. RATHKE: I would not have brought it to the Court's attention.

THE COURT: No, I understand that. It's something you weren't able to previously work out. I get that.

MR. BOTTARO: Excuse me, Judge.

THE COURT: Yes.

MR. BOTTARO: If I could raise -- you asked earlier about raising maybe some solutions or something. This is regarding the area of your considering sanctions regarding the handling of objections or handling deposition testimony.

THE COURT: Yeah.

MR. BOTTARO: Yesterday during the cross-examination by Mr. Reidy of Dr. Donnelly, Scott Donnelly, it appeared in the use of the Sharon Bottock deposition -- it became clear to me at least that I think next week they're going to bring Ms. Bottock in, and there were intimations made I think by Counsel Reidy as to whether or not Mr. -- Dr. Donnelly had reviewed, had his facts correct and things like that, and I thought there were intimations as to whether or not he might be misrepresenting or be just wrong in what he knew based upon his reading of Sharon Bottock's deposition.

And as we looked at those sections of the record that he was asking about, Dr. Donnelly testified it was so confusing he wasn't sure what she said.

THE COURT: Right.

MR. BOTTARO: So it appears to me next week Ms. Bottock is going to come in and try to clear all of this up and it will make it look like Dr. Donnelly either was misrepresenting facts or didn't understand them.

And I'm suggesting that if the Court looks at Ms. Bottock's deposition and comes to the conclusion as I have that because of the objections and the statements by Abbott's counsel it would cause Dr. Donnelly or anyone else to have similar confusion that if the Court considered barring Ms. Bottock from either testifying or at least testifying to

that section which starts at page 95 of the deposition and goes through page 100, that would be a way to look at handling a sanction for that kind of conduct. In other words, if --

THE COURT: Wait. Wait, wait, wait. Just a second.

MR. BOTTARO: All right.

THE COURT: Your witness claims he couldn't understand the deposition testimony and was confused by it.

MR. BOTTARO: Yes.

THE COURT: They have every right to call Miss Bottock, no s, and if she testifies differently than her deposition, then you impeach her with the deposition or the fact that she's now testifying to something she didn't testify to, and then they can argue, well, she wasn't asked that and all of that. But what I understand you to be asking me is you want me to somehow limit a witness to their deposition testimony because some other witness claims they were confused by it. Am I missing something?

MR. BOTTARO: I think you might be, Your Honor. The point I'm trying to make -- and I didn't make it clearly obviously.

THE COURT: And how does that have anything to do with sanctions?

MR. BOTTARO: I think that if the Court reads the testimony beginning at page 95 through 100 and sees why the witness was confused because of the interruptions or the

objections or the outright testimony by opposing counsel, then if they get to bring in a witness to then try to clarify everything that sounds completely reasonable without those objections, then they seem to be rewarded by their bad behavior.

THE COURT: Okay. Now I'm at least tracking you. And assuming --

MS. GHEZZI: Your Honor, may I say something?

THE COURT: Yeah. You'll have -- I'll give you plenty of opportunity. But isn't the rem -- so what are you asking for a remedy?

MR. BOTTARO: What I'm asking is if the Court agrees at least on the portion that he was cross-examined on that the actions of opposing counsel were such that it's reasonable for Dr. Donnelly to have been confused and not be able to testify, then they should be barred from making it look like he didn't understand because he didn't understand based upon the objections and the interruptions by counsel telling the witness how to testify.

THE COURT: Okay. Let's back up. And I want to hear from the defense. But first I would have to find that those objections were impermissible.

MR. BOTTARO: Correct.

THE COURT: Can't assume that they are.

MR. BOTTARO: That's correct.

THE COURT: Then if I found that those objections were

impermissible and somehow I'm supposed to guess that that affected Mr. Donnelly's ability to understand it which would be difficult for me to do -- I could make a judgment about whether I could understand it -- wouldn't the remedy be for you to put in the deposition and question the witness about all the interruptions and how it might be confusing for somebody else reading it or to put in the deposition and then be able to argue that to the jury in closing argument? Wouldn't that be the remedy?

MR. BOTTARO: That could be a remedy.

THE COURT: Yeah.

MR. BOTTARO: Another remedy could be to say --

THE COURT: Well, I guess I could dismiss the case. That could be a remedy. Or I -- I mean -- I'm sorry, enter judgment for the pl -- I mean, but wouldn't that -- wouldn't the more logical remedy be for you to be able to show that deposition to the witness or ask the witness about all the objections and how that might be confusing?

MR. BOTTARO: That would be one way to handle it, yes, Your Honor.

THE COURT: Okay. But first I'd have to find out that there was something objectionable about it.

MR. BOTTARO: Well, that's what I was asking the Court to --

THE COURT: Yeah. And so what pages are you --

MR. BOTTARO: Well, starting -- the testimony, as I understand it, the line of questioning starts on page 95 and goes until about the middle of page 100.

THE COURT: Okay.

MR. BOTTARO: And I believe Dr. Donnelly did testify that he wasn't able to make heads or tails of what she --

THE COURT: No. He did say something like that.

Now, let me hear from the defense. Miss Ghezzi or . . .

MS. GHEZZI: Your Honor, I haven't -- June Ghezzi for the record. I haven't read the whole deposition here. I was looking at 95 through 100. I can tell you that in the course of our depositions what was standard procedure was that if -- whatever side was asking a question -- in this case a series of questions that Mr. Rathke was asking an Abbott witness that was highly technical where we had a lot of documents on the table and he would ask a question about, well, what's this and where does this go, I can even show you some of these where you can't tell --

THE COURT: No, I've read some of them. Sometimes you do an admirable job of asking a better question.

MS. GHEZZI: Thank you, Your Honor. But, I mean --

THE COURT: I'm not sure that's your role, but you did it.

MS. GHEZZI: Well, we did it a lot.

THE COURT: Right.

MS. GHEZZI: And the reason we did it a lot was to move things along. It was -- and I'm not blaming him. The issue was the documents are -- they're technical. They're hard to read. The writing is in pencil. He couldn't see it. We couldn't see it. Sometimes it looks like it's above the /// zone. Sometimes it looks like it's in the dryer, you know, and they were confusing. And the whole -- the whole point of it was to move the deposition along and to do it in a way where I was trying to make sure that the two of them were talking to each other -- and I can say that in every case that I've had with Mr. Rathke in this kind of a situation, there was this sort of understanding that, yeah, you don't have to wait till the end of the deposition and then clarify it. If there's something you want to clarify now, go ahead and ask her the question now. That was the way we did it in other cases, and it's the way we did it in this case.

And he didn't object to my questioning her here. And when we were doing it, you know, it made more sense. And so then we were able to go on to the next part. But if he didn't understand what was happening, then I did object to the question and I did object to the form because it was so confusing, you can't even tell what document --

THE COURT: Wait. Now who's the he? Mr. Rathke?

MS. GHEZZI: Yes.

THE COURT: Yeah, okay.

MS. GHEZZI: You couldn't even tell what document we were talking about sometimes. And so it was unfair to the witness. And, you know, my job was to sort of facilitate that. I understand it may not look like that, but that's what was happening.

THE COURT: Well, sometimes it looks like that.

MS. GHEZZI: Okay.

THE COURT: No. Sometimes it does.

MS. GHEZZI: And this is one of those situations where, you know, he couldn't make head nor tails of it and I think, you know, didn't have -- you know, I have the benefit of being able to talk to the Abbott people about what these documents mean.

THE COURT: Sure.

MS. GHEZZI: And he doesn't have the opportunity to talk to somebody, so he doesn't know what they mean, and he's trying to ask questions, and we're trying to facilitate it. That's what's going on.

THE COURT: You know, here's the deal. I have a sentencing at three o'clock which I want to get ready for. I have the deposition right in front of me, and I'll look at it, and we can talk about it first thing in the morning.

MR. REIDY: And, Judge, may I also offer to hand up Exhibit 54 and to suggest to the judge one other page to look at

because I did this witness that we're talking about, Mr. Donnelly, and I would only say, Judge, that --

THE COURT: 54 of Bottock's deposition?

MR. REIDY: No, it actually is I think -- it's 54. I have a copy in my hand. I'm going to hand it up to the Court. It's 54 in this. I think it might be 54, 55, both. But I'll hand it up to the Judge.

THE COURT: Of what now? 54, 55 of what? That's what I'm confused about.

MR. REIDY: I have Plaintiff's Exhibit 54 from the trial which is the exhibit that they were using at the time -- they may call it something else.

THE COURT: I see.

MR. REIDY: It's -- only the exhibit matters. And I would only say to the judge that as you look down the left side, there's -- when it gets to the /// zone, there's something called the powder heat treatment. And much of the discussion is to figure out whether or not that's liquid or powder.

THE COURT: Powder.

MR. REIDY: And how hot it is, and that was the subject matter, and because it's in the dryer building, there was some assumption going on that it must be dry heat. It's not. And it took a while. The witness maintains a pretty steady understanding of what it is I think you'll find. Anyway, I'll hand this up to the Court. You can have a look.

THE COURT: Thank you very much. Thank you.

MR. REIDY: Thank you, Judge.

THE COURT: Okay. Anything else?

MR. RATHKE: No, Your Honor.

THE COURT: Okay.

MR. REIDY: Thank you, Judge.

THE COURT: We'll see you tomorrow morning.

(The foregoing trial was adjourned at 2:45 p.m.)

CERTIFICATE

I certify that the foregoing is a correct copy of the transcript originally filed with the Clerk of Court on 3-20-14 incorporating redactions of personal identifiers and any other redactions ordered by the Court in accordance with Administrative Order 08-AO-0009-P.

S/Shelly Semmler
Shelly Semmler, RMR, CRR

5-6-14
Date

INDEX

*****